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Validation of the electronic version of the BREAST-Q in the army of women study

Sarah Fuzesi, MD^{a,*}, Stefan J. Cano, PhD^b, Anne F. Klassen, DPhil^c, Dunya Atisha, MD^d, and Andrea L. Pusic, MD^a

^aMemorial Sloan Kettering Cancer Center, 1275 York Ave, New York, NY 10065, USA

^bModus Outcomes, Spirella Building, Letchworth Garden City, SG6 4ET, UK

^cMcMaster University, 3N27, 1200 Main Street W, Hamilton, ON L8N 3Z5, Canada

^dHenry Ford Health System, 2799 W. Grand Blvd, K-16, Detroit, MI 48202, USA

Abstract

Women undergoing surgery for primary breast cancer can choose between breast conserving therapy and mastectomy (with or without breast reconstruction). Patients often turn to outcomes data to help guide the decision-making process. The BREAST-Q is a validated breast surgery-specific patient-reported outcome measure that evaluates satisfaction, quality of life, and patient experience. It was originally developed for paper-and-pencil administration. However, the BREAST-Q has increasingly been administered electronically. Therefore, the aim of this study was to evaluate the psychometric properties of an electronic version of the BREAST-Q in a large online survey. Women with a history of breast cancer surgery recruited from the Love/AVON Army of Women program completed an electronic version of the BREAST-Q in addition to the Impact of Cancer Survey and PTSD Checklist. Traditional psychometric analyses were performed on the collected data. BREAST-Q data were collected from 6748 women (3497 Breast Conserving Therapy module, 1295 Mastectomy module, 1956 Breast Reconstruction module). Acceptability was supported by a high response rate (82%), low frequency of missing data (<5%), and maximum endorsement frequencies (<80%) in all but 17 items. Scale reliability was supported by high Cronbach's α coefficients (0.78) and item-total correlations (range of means, 0.65–0.91). Validity was supported by interscale correlations, convergent and divergent hypotheses as well as clinical hypotheses. The electronically administered BREAST-Q yields highly reliable, clinically meaningful data for use in clinical outcomes research. The BREAST-Q can be used in the clinical

*Corresponding author. Department of Surgery, Memorial Sloan Kettering Cancer, Center, 1275 York Ave, New York, NY 10065, USA. fuzesis@mskcc.org (S. Fuzesi).

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Disclosures

Drs. Cano, Klassen, and Pusic are co-developers of the BREAST-Q and receive royalties when it is used in industry-sponsored, for-profit clinical trials.

Ethical Approval

The Army of Women Scientific Advisory Committee accepted this study with ethics approval obtained from the Duke University Medical Center Institutional Review Board and the Cancer Protocol Committee in June 2012.

setting, whether administered electronically or using paper-and-pencil, at the choice of the patient and surgeon.

Keywords

BREAST-Q; PROMS; Patient reported outcome measures; Patient reported outcomes; Psychometrics; Electronic questionnaires; Breast surgery

INTRODUCTION

Breast cancer is the second most common cancer among women in the United States, with an estimated 246,660 new diagnoses projected in 2016 [1]. Owing to advances in the field of surgical oncology, breast cancer patients and survivors now have many surgical options, which emphasizes the importance of understanding the long-term quality of life (QOL) outcomes [2]. Women undergoing surgery for primary breast cancer are increasingly making their own surgical decisions, and are often choosing between breast conserving therapy and mastectomy with or without breast reconstruction [3]. Although recent studies suggest breast conserving therapy has a survival benefit [4], patients often turn to satisfaction and QOL outcomes data to help guide the decision-making process [5, 6].

Patient-reported outcome measures (PROMs) are increasingly used in clinical research, education, and patient care. The field of PRO measurement is expanding, and the number of condition-specific scales continues to grow. As such, the COnsensus-based Standards for the selection of health Measurement INstruments initiative has suggested guidelines for the validation of PROMs [7]. Hospitals and clinics are incorporating PROMs into patient care and are more frequently capturing them in electronic medical records. It is therefore critical that electronically administered PROMs are demonstrated to have comparable psychometric validity to the paper-and-pencil version [8].

The BREAST-Q is a validated breast surgery—specific PROM that assesses patient satisfaction, QOL, and patient experience within breast surgery—specific domains [9, 10]. The BREAST-Q can provide meaningful data that can be used to support quality metrics and evidence-guided surgical practices in oncologic breast and plastic surgery [11]. It has been widely used by clinicians and researchers to help patients and surgeons better understand outcomes [9–12]. A recent literature review identified 49 publications that used the BREAST-Q as an outcome measure, including 22,457 patients who completed at least one scale of the BREAST-Q [12]. For example, the BREAST-Q was used to compare satisfaction with silicone and saline implant reconstruction after mastectomy; this analysis revealed that satisfaction with the breast was higher among those who received silicone implants [13]. Another study reported psychosocial and sexual well-being after nipple-sparing and skin-sparing mastectomies with reconstruction and found that nipple-sparing mastectomy was associated with higher QOL [14]. Other researchers used the BREAST-Q to evaluate the effect of a decision aid for different breast reconstruction options [15]. An increasing number of cancer hospitals have incorporated the BREAST-Q into clinical care. At these hospitals, physicians use the BREAST-Q in routine clinical practice to follow the progress of individual patients.

The BREAST-Q was originally developed and validated using a paper-and-pencil approach [9]. Given the uptake of the BREAST-Q in research and clinical practice, it is necessary to examine its psychometric performance when data are collected in an electronic format. The aim of this study was to examine the performance and clinical relevance of the BREAST-Q in an online community and to assess the psychometric validity of web-based completion.

METHODS

Study Design

A sample of participants were recruited from the Army of Women (AOW), an online community started in 2008 by the Dr. Susan Love Research Foundation with the goal of connecting breast cancer researchers to women with and without breast cancer [11]. The AOW Scientific Advisory Committee accepted this study, as previously described, with ethics approval obtained from the Duke University Medical Center Institutional Review Board and the Cancer Protocol Committee in June 2012 [16].

A recruitment e-mail (e-blast) was sent to AOW members, with a follow-up e-mail sent to eligible and interested participants. Women were invited to participate if they had undergone surgery for breast cancer and were able to complete the surveys in English. Participants completed a demographic survey and were directed to take either the BREAST-Q Breast Conserving Therapy, BREAST-Q Mastectomy, or BREAST-Q Breast Reconstruction postoperative module on the basis of their responses to demographic questions. Patients who completed the Breast Reconstruction module but had revision reconstruction surgery or had undergone surgery after recurrence were excluded from this validation study, as their experience was complex and could confound results. In addition to the BREAST-Q, participants also completed the Impact of Cancer Version 2 [17, 18] and the PTSD Checklist-Civilian version (PCL-C) [19, 20]. These two breast cancer-specific PROMs were used to establish construct validity via comparisons with the BREAST-Q scales.

Measures

BREAST-Q—The BREAST-Q was designed to assess the unique outcomes of breast surgery patients. The originally described core domains, which were identified through patient interviews, were physical well-being, psychosocial well-being, sexual well-being, satisfaction with breast, satisfaction with outcome, and satisfaction with care. Modules specific to different types of breast surgery were developed, with scales measuring different domain constructs. For example, the Breast Reconstruction module contains a different satisfaction with breast scale than the Breast Conserving Therapy module. Items for each scale are evaluated with multiple response options. Raw scores are added and converted to a score from 0 (worse) to 100 (best). In the original BREAST-Q development study and subsequent psychometric validation study, BREAST-Q data were collected via postal surveys sent to breast surgery patients [9, 21]. The BREAST-Q was developed using Rasch measurement theory analysis. Paper-based assessments have demonstrated high internal consistency, with a Cronbach's α of 0.81–0.97, and test-retest reproducibility, as measured by intraclass correlation coefficients of 0.73–0.96, for each scale within the modules [9].

Impact of Cancer Version 2—The Impact of Cancer Version 2 is a 47-item questionnaire intended to assess the effect that cancer has had on the health-related QOL of long-term survivors [17, 18]. The questionnaire consists of two higher-order scales, the positive impact summary scale and the negative impact summary scale, each with four scales. The negative impact summary has the following scales: appearance concerns, body change concerns, life interference, and worry. For each item, respondents indicate his or her agreement with five response options that range from “strongly disagree” to “strongly agree.” The scale scores represent the mean of the item responses within the scale. High scores represent a higher impact; high negative impact scores are worse than low negative impact scores. The negative impact and positive impact summary score is a mean of the scale scores. The Impact of Cancer Version 2 has demonstrated high internal consistency (Cronbach’s α statistics, 0.76–0.89) when distributed by mail to survivors of early-stage breast cancer [18].

PCL-C—The PCL-C is a self-administered checklist of key symptoms of posttraumatic stress disorder (PTSD) in the civilian population and consists of 17 items that correspond to the Diagnostic and Statistical Manual of Mental Disorders 4th ed. [19]. The items address four distinct characteristics of PTSD: re-experiencing, avoidance, numbing, and hyperarousal. Respondents indicate how bothered by a symptom they have been during the past month using a 5-point scale, ranging from “not at all” (1 point) to “extremely” (5 points). Items are summed to produce a total PTSD severity score. The instrument has been used previously to assess symptoms of PTSD in breast cancer survivors [22, 23]. The PCL-C has shown high internal consistency among domestic violence victims [24], college students who have experienced trauma [20], and bone marrow transplant patients [25] when completed in person, by mail, and by telephone interview. The Cronbach’s α for the total score in these populations ranged from 0.89 to 0.94 [20, 24, 25].

Statistical Analysis

Scores for the electronically administered BREAST-Q were computed for each scale of the three procedure-specific modules on the basis of the BREAST-Q scoring tables. Scores were excluded from the analysis if any item included in the scale was missing. With two exceptions, all scales were completed by the entire sample (women who had abdominal surgery were the only patients to complete the physical well-being—abdomen and satisfaction with abdomen scales). In the evaluation of the performance of the electronically administered BREAST-Q, traditional psychometric methods were used in accordance with international instrument guidelines for data quality, reliability, and validity [10, 26].

For reliability, internal consistency was tested by computing the Cronbach’s α coefficient for each scale supported by values >0.70 [26–28]. Internal consistency was also tested by measuring the correlation of single items to the total score supported by values >0.30 [9, 28]. Acceptability was determined by examining maximum endorsement frequencies (MEFs) and missing data. For each item response, the proportion of respondents was determined, and a MEF $>80\%$ was considered a violation, in accordance with the traditional psychometric approach. For each item, the proportion of missing responses $>5\%$ was

considered a violation [9, 28]. Construct, convergent, and clinical validity were tested as described below.

Construct Validity—Construct validity was evaluated by measuring interscale correlations to determine the agreement between separate but related constructs. Validity was supported by Spearman's coefficients of 0.30–0.70 [28, 29].

Convergent Validity—The convergent validity of each scale was tested by measuring correlations between scale scores and previously validated scales (PCL-C and negative impact summary scale with appearance concerns, body change concerns, life interference, and worry scales). We measured only correlations with the IOCV2 that had items related to the BREAST-Q scales. Hypotheses were made on the basis of the constructs within each external scale as they related to the BREAST-Q constructs. For example, we hypothesized that the satisfaction with breast scale and the appearance concerns scale would be correlated, as they both measure similar surgical outcomes. Moderate correlations were supported by absolute Spearman's coefficients of 0.30–0.70 [28]. Discriminant validity was tested by measuring correlations of scale scores between clinical groups without known differences (age, education), with low correlations supported by Spearman's coefficients <0.30 [28].

Clinical Validity—Finally, the ability of the scales to differentiate between known clinical subgroups was tested using the Wilcoxon signed rank sum test. As adjuvant chemotherapy has been shown to negatively affect the functional and aesthetic outcomes of breast conserving therapy, we hypothesized that, among patients who underwent breast conserving therapy, scores for participants who received adjuvant chemotherapy would be lower than those for patients who received no chemotherapy [30]. We also compared scores between patients who had free and pedicle transverse rectus abdominis muscle (TRAM) flap procedures and patients who had implant-based reconstruction. Previous evidence suggests that patients are more satisfied with TRAM flap reconstruction than with implants [31]. In addition, we hypothesized that scores for patients who self-reported complications would be lower than those for patients who experienced no complications, which has been shown in previous work [6]. Complications included bleeding, open wounds, infections requiring antibiotics, scarring, seroma, infection of implants requiring removal, fat necrosis requiring removal, failed reconstruction requiring different reconstruction, partial loss of flap, and complete loss of flap. Respondents selected all complications that they experienced. We dichotomized respondents into those who reported at least one complication and those who reported no complications.

RESULTS

As previously reported, 7619 women consented to and completed the AOW survey (response rate, 82%) [16]. In total, 6748 women were included in this evaluation. Demographic data and available clinical data for the procedure-specific groups are listed in Table 1: breast conserving therapy (52%; n=3497), mastectomy (19%; n=1295), and breast reconstruction (29%; n=1956). Most women were postmenopausal (mean age, 58 years; SD, 9.4; range, 18–70), white (94%), married (71%), and had some higher education (95%). Most were

treated for stage 1 or 2 breast cancer (77%) and did not have a recurrence (94%). Twenty-nine percent experienced a complication (Table 1).

The internal consistency of each scale score for the BREAST-Q was supported by high Cronbach's α coefficients (0.78–0.96) and high item-total correlations (range of means, 0.65–0.91). Missing data was low for each item within the scales, with no items having >5% missing data (Table 2). Seventeen of 205 items had a MEF >80%; otherwise, the items met the criteria for acceptability.

Construct validity was supported by interscale correlations with moderate to high Spearman's coefficients (breast conserving therapy, 0.21–0.64; mastectomy, 0.34–0.69; breast reconstruction, 0.22–0.73) (Table 2).

Hypotheses of relationships between the breast conserving therapy scales and external instrument scales were supported by moderate correlations (0.31–0.62). One correlation was lower than expected: body change concerns and satisfaction with breast (0.29). Hypotheses of correlations between the mastectomy scales and external instrument scales were supported by moderate correlations (0.46–0.70). Hypotheses of correlations between the breast reconstruction scales and other instrument scales were supported by moderate correlations (0.31–0.71). Three correlations were lower than expected: worry and satisfaction with outcome, worry and satisfaction with information, and negative impact summery scale and satisfaction with info (0.14 and 0.18). Discriminant validity was supported with low coefficients in each module with two variables (0.00–0.22) (Table 3).

Clinical hypotheses are summarized in Table 4. Differences between scores for women who reported any complications were significant for all scales in every procedure-specific module ($p<0.01$). Among the women who received breast conserving therapy, those who received adjuvant therapy had lower scores for all scales ($p<0.01$) except adverse effects of radiation ($p=0.48$). Women who received either a free or pedicle TRAM flap had higher scores in the breast reconstruction scales than women who received implants ($p<0.01$), with the exception of the satisfaction with information scale ($p=0.11$).

DISCUSSION

In this study, the Breast Conserving Therapy, Mastectomy, and Breast Reconstruction modules of the BREAST-Q were shown to have reliability, validity, and clinical relevance when administered electronically. Building on the expansive use of the BREAST-Q in clinical research, quality measurement, and clinical practice, these analyses support the validity and reliability of the electronically administered version. The e-version of the BREAST-Q scales were shown to be valid in a breast cancer population and to fulfill the criteria for published psychometric guidelines.

Our study highlights the benefits of using an electronic survey. Sending surveys via email allows patients to complete them at the time and place of their choosing, and results in high response rates. Patients can answer questions about satisfaction with breast and sexual well-being, for example, in the privacy of their own home. A large sample of patients can be included and results are delivered instantly and accurately. Surveys can be tailored to

individual patient experiences or surgery type like we have demonstrated in this study. Breast surgeons can incorporate the BREAST-Q with a variety of scales and procedures into their practice, with the click of a button.

Further study of the electronic BREAST-Q will be directed toward evaluating test-retest reliability, as well as responsiveness. We also anticipate considering the utility of computer adaptive testing for the BREAST-Q. The computer adaptive testing version will allow patients to answer fewer but more-specific and-informative questions, giving clinicians and researchers information in a more efficient manner.

This study has several strengths. Performing recruitment through the AOW resulted in a large sample size and a diverse population not limited to a single institution or region. This methodology allowed for the evaluation of subgroups based on type of surgery, treatment, and time from surgery. Another strength was the study's inclusion of only cancer patients, which eliminated confounders associated with cancer such as anxiety and depression. This study used scales that had previously been validated for the paper form of the survey, and, therefore, we were able to compare psychometric properties between the paper and electronic formats.

A limitation of this study was that participation was voluntary and only interested participants of the AOW were offered the survey. Moreover, the AOW participants were mostly white, educated, upper-middle-class women, which is reflected in our population. Another limitation relates to the length of time that had passed since breast cancer treatment for some participants. For those who were longer out from their surgery, some recall bias may be present for the scales asking about satisfaction with information and surgeon. Furthermore, clinical data were provided by the participants and could not be confirmed through medical records. As we did not evaluate test-retest reliability in this study, we cannot comment on consistency over time for electronic administration. In addition, the sample was cross-sectional, and we were therefore unable to demonstrate the responsiveness of the BREAST-Q to clinical change [13, 14].

Conclusions

We have shown that the electronically administered BREAST-Q is psychometrically valid. For each scale, evidence demonstrated validity, reliability, and acceptability. These scales can be used in clinical practice for patient evaluation and education or as primary outcomes in quality and outcomes research. The BREAST-Q continues to be a valuable tool to inform and support clinical care, comparative effectiveness research, and quality improvement for patients with breast cancer.

Abbreviations

AOW	Army of Women
MEF	maximum endorsement frequency
PCL-C	PTSD Checklist-Civilian version

PROM	patient-reported outcome measure
PTSD	posttraumatic stress disorder
QOL	quality of life
TRAM	transverse rectus abdominis muscle

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HIGHLIGHTS

- The BREAST-Q is a validated breast surgery-specific patient-reported outcome measure that has been validated in electronic format.
- Psychometric evaluation of the BREAST-Q provided evidence that the BREAST-Q is acceptable, valid and reliable in an electronic distribution.
- The BREAST-Q can be administered electronically in clinical outcomes research and yields clinically meaningful data.
- The BREAST-Q can be used in the clinical setting, whether administered electronically or using paper-and-pencil, at the choice of breast cancer patients and their surgeon.

Table 1

Patient demographic and clinical characteristics

Characteristic	All (n=6748)	Procedure-specific groups		
		Breast-conserving therapy (n=3497)	Mastectomy (n=1295)	Breast reconstruction (n=1956)
Age, years, mean (SD)	58 (9.4)	59 (8.9)	61 (9.2)	55 (9.3)
Stage				
1	3155 (47)	1886 (54)	385 (30)	884 (45)
2	2025 (30)	986 (28)	428 (33)	611 (31)
3	638 (9)	180 (5)	281 (22)	177 (9)
4 or metastatic disease	90 (1)	26 (1)	41 (3)	23 (1)
Unknown	840 (12)	409 (12)	160 (12)	261 (13)
Type of breast cancer				
Ductal carcinoma in situ	2035 (30)	1087 (31)	291 (22)	656 (34)
Invasive ductal carcinoma	2649 (39)	1393 (40)	507 (39)	748 (38)
Invasive lobular carcinoma	401 (6)	174 (5)	85 (7)	142 (7)
Other/Unknown	1666 (25)	843 (24)	412 (32)	410 (21)
Recurrence				
Yes	369 (5)	62 (2)	132 (10)	175 (9)
No	6334 (94)	3405 (97)	1161 (90)	1768 (90)
Complications				
Yes	1938 (29)	789 (23)	397 (31)	752 (39)
No	4803 (71)	2706 (77)	897 (69)	1200 (61)
Marital status				
Married/Significant other	5114 (76)	2617 (75)	935 (72)	1562 (80)
Widowed/Separated/Divorced	1143 (17)	600 (17)	265 (20)	278 (14)
Single, never married	474 (7)	272 (8)	93 (7)	109 (6)
Education				
High school	336 (5)	173 (5)	85 (7)	78 (4)
College, trade, university	3639 (54)	1878 (54)	675 (52)	1086 (56)
Master/Doctoral degree	2754 (41)	1436 (41)	531 (41)	787 (40)
Employment				
Full-time	2551 (38)	1313 (38)	386 (30)	852 (44)
Part-time	984 (15)	504 (14)	183 (14)	297 (15)
Retired	1629 (24)	920 (26)	411 (32)	298 (15)
Other	1567 (23)	747 (21)	313 (24)	507 (26)
Race				
White, Non-Hispanic	6163 (91)	3216 (92)	1178 (91)	1769 (90)
White, Hispanic	87 (1)	43 (1)	16 (1)	28 (1)
Black or African American	16 (2)	51 (1)	27 (2)	28 (1)
Asian or Pacific Islander	65 (1)	34 (1)	16 (1)	15 (1)
Other	317 (5)	153 (4)	58 (4)	106 (5)
Years from surgery				

Characteristic	All (n=6748)	Procedure-specific groups		
		Breast-conserving therapy (n=3497)	Mastectomy (n=1295)	Breast reconstruction (n=1956)
<5	3061 (45)	1594 (46)	507 (39)	960 (49)
5–10	1663 (25)	951 (27)	279 (22)	433 (22)
11–15	969 (14)	501 (14)	218 (17)	250 (13)
16–20	480 (7)	214 (6)	126 (10)	140 (7)
>20	302 (4)	99 (3)	126 (10)	77 (4)

Table 2

Summary of classical test theory psychometrics

Module/scale	Items, no.	Cronbach's α coefficient	Item-total correlations, mean (range)	Inter-scale Spearman's coefficient, range	Missing data %, range of maximums	MEF %, range of maximums
BREAST-Q Breast Conserving Therapy module						
Satisfaction with Breast	11	0.96	0.83 (0.75–0.89)	0.22–0.57	0.1–1.0	33–68
Adverse effects of radiation	7	0.80	0.67 (0.58–0.73)	0.25–0.39	0.5–1.2	72–83
Psychosocial well-being	10	0.95	0.85 (0.79–0.89)	0.32–0.64	0.3–0.7	46–76
Sexual well-being	8	0.93	0.83 (0.59–0.89)	0.30–0.64	0.5–1.7	20–38
Physical well-being	14	0.89	0.65 (0.41–0.74)	0.21–0.36	0.2–1.5	44–81
Satisfaction with information	12	0.93	0.76 (0.70–0.83)	0.21–0.49	0.2–1.9	41–76
BREAST-Q Mastectomy module						
Satisfaction with breast	4	0.82	0.81 (0.73–0.86)	0.44–0.67	0.2–4.9	31–41
Psychosocial well-being	10	0.95	0.85 (0.81–0.87)	0.44–0.69	0.1–0.8	32–62
Sexual well-being	6	0.94	0.72 (0.52–0.82)	0.34–0.69	0.3–1.5	26–49
Physical well-being	16	0.93	0.87 (0.78–0.93)	0.34–0.44	0.2–1.5	43–83
BREAST-Q Breast Reconstruction module						
Satisfaction with breast	16	0.96	0.78 (0.69–0.84)	0.33–0.68	0.4–2.3	33–59
Satisfaction with outcome	7	0.89	0.79 (0.75–0.84)	0.32–0.68	1.2–1.5	43–82
Psychosocial well-being	10	0.96	0.85 (0.78–0.89)	0.28–0.73	0.2–0.7	35–64
Sexual well-being	6	0.94	0.87 (0.75–0.93)	0.31–0.73	0.5–1.6	29–43
Physical well-being	16	0.92	0.69 (0.49–0.79)	0.22–0.53	0.3–1.5	44–83
Physical well-being (abdomen)	8	0.88	0.74 (0.61–0.84)	0.28–0.53	1.8–2.8	48–75
Satisfaction with abdomen	3	0.78	0.83 (0.82–0.85)	0.28–0.47	1.9–2.5	35–50
Satisfaction with information	15	0.95	0.76 (0.68–0.81)	0.22–0.33	0.2–1.7	33–77
Common scales						
Satisfaction with surgeon	12	0.97	0.87 (0.76–0.92)	—	0.2–0.7	72–88
Satisfaction with medical team	7	0.96	0.91 (0.87–0.93)	—	1.4–2.0	77–85
Satisfaction with office staff	7	0.96	0.91 (0.87–0.93)	—	1.3–1.8	77–84

MEF, maximum endorsement frequency.

Table 3

Convergent and discriminant construct validity of the BREAST-Q

Module/scale	PCL-C [19]	Negative impact scale	Negative impact of cancer subscales [17]				Worry	Age	Education
			Appearance concerns	Body change concerns	Life interference				
BREAST-Q Breast Conserving Therapy module									
Satisfaction with breast	.29	.34 [†]	.57 [†]	.29 [†]	.26	.18	.03 [^]	.13 [^]	
Adverse effects of radiation	.36 [†]	.36 [†]	.31 [†]	.35 [†]	.3	.24	.17 [^]	.08 [^]	
Psychosocial well-being	.55 [†]	.57 [†]	.62 [†]	.48 [†]	.50 [†]	.39 [†]	.21 [^]	.09 [^]	
Physical well-being	.37	.35 [†]	.27	.36 [†]	.32 [†]	.25	.18 [^]	.09 [^]	
Sexual well-being	.50 [†]	.54 [†]	.61 [†]	.47 [†]	.47	.35	.14 [^]	.11 [^]	
Satisfaction with information	.31	.33 [†]	.41	.26	.28	.22 [†]	.05 [^]	.03 [^]	
BREAST-Q Mastectomy module									
Satisfaction with breast	.47	.53 [†]	.64 [†]	.46 [†]	.46	.37	.15 [^]	.13 [^]	
Psychosocial well-being	.62 [†]	.67 [†]	.70 [†]	.54 [†]	.60 [†]	.51 [†]	.22 [^]	.10 [^]	
Physical well-being	.53	.51 [†]	.37	.53 [†]	.46 [†]	.40	.17 [^]	.13 [^]	
Sexual well-being	.54 [†]	.62 [†]	.66 [†]	.53 [†]	.56	.48	.10 [^]	.13 [^]	
BREAST-Q Breast Reconstruction module									
Satisfaction with breast	.34	.39 [†]	.58 [†]	.35 [†]	.32	.23	.00 [^]	.05 [^]	
Satisfaction with outcome	.31 [†]	.34 [†]	.47 [†]	.32	.30 [†]	.18 [†]	.03 [^]	.03A	
Psychosocial well-being	.59 [†]	.63 [†]	.71 [†]	.54 [†]	.56 [†]	.42 [†]	.20 [^]	.06A	
Physical well-being	.50	.45 [†]	.36	.46 [†]	.42 [†]	.33	.15 [^]	.11 [^]	
Sexual well-being	.50 [†]	.54 [†]	.66 [†]	.46 [†]	.48	.35	.05 [^]	.07 [^]	
Physical well-being (abdomen)	.36	.39 [†]	.31	.43 [†]	.34 [†]	.27	.11 [^]	.12 [^]	
Satisfaction with abdomen	.33	.37 [†]	.46 [†]	.38 [†]	.27	.25	.08 [^]	.09 [^]	
Satisfaction with information	.23	.21 [†]	.26	.18	.18	.14 [†]	.01 [^]	.08 [^]	

Shown are absolute values by Spearman correlation. All correlations were included for completeness. Hypotheses tested are indicated with the symbols described below. PCL-C, PTSD Checklist-Civilian Version.

[†]Correlations were consistent with predictions.

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*Correlations were lower than predicted.
^Discriminant correlations were consistent with predictions.

Table 4

Clinical validity hypothesis testing

Module/scale	Any complication Med, (IQR)	No complication Med, (IQR)	p	Adjuvant therapy Med, (IQR)	No adjuvant therapy Med, (IQR)	p	Implant reconstruct on Med, (IQR)	TRAM reconstruct on Med, (IQR)	p
BREAST-Q Breast Conserving Therapy module	n= 789	n= 2706		n= 1662	n= 1651				
Satisfaction with breast	55 (41–71)	66 (50–85)	<0.01	62 (44–77)	66 (50–80)	<0.01	—	—	—
Adverse effects of radiation	89 (73–100)	100 (80–100)	<0.01	89 (80–100)	89 (80–100)	0.48	—	—	—
Psychosocial well-being	76 (61–100)	87 (65–100)	<0.01	78 (63–100)	82 (68–100)	<0.01	—	—	—
Physical well-being	72 (62–86)	78 (67–92)	<0.01	75 (64–86)	77 (67–92)	<0.01	—	—	—
Sexual well-being	52 (40–63)	58 (46–69)	<0.01	55 (42–66)	60 (48–69)	<0.01	—	—	—
Satisfaction with information	64 (52–79)	75 (58–100)	<0.01	70 (56–84)	74 (58–100)	<0.01	—	—	—
BREAST-Q Mastectomy module	n= 397	n= 897							
Satisfaction with breast	49 (38–61)	52 (44–71)	<0.01	—	—	—	—	—	—
Psychosocial well-being	63 (52–78)	70 (57–87)	<0.01	—	—	—	—	—	—
Physical well-being	72 (57–86)	78 (69–92)	<0.01	—	—	—	—	—	—
Sexual well-being	41 (26–54)	45 (30–60)	0.014	—	—	—	—	—	—
BREAST-Q Breast Reconstruction module	n= 752	n= 1200					n= 1547	n= 669	
Satisfaction with breast	60 (46–74)	63 (51–76)	<0.01	—	—	—	59 (47–71)	70 (57–86)	<0.01
Psychosocial well-being	70 (65–87)	76 (59–92)	<0.01	—	—	—	72 (55–92)	79 (63–100)	<0.01
Physical well-being	75 (63–86)	78 (69–86)	<0.01	—	—	—	76 (66–86)	79 (69–92)	<0.01
Sexual well-being	48 (35–64)	52 (37–64)	<0.01	—	—	—	49 (35–64)	55 (41–68)	<0.01
Physical well-being (abdomen)	80 (60–90)	90 (71–100)	<0.01	—	—	—	—	—	—
Satisfaction with abdomen	61 (44–71)	71 (52–84)	<0.01	—	—	—	—	—	—
Satisfaction with information	59 (48–74)	64 (48–77)	<0.01	—	—	—	63 (48–74)	65 (48–77)	0.11

Shown are the results of comparison of scores between clinical groups. *p* values were derived using the Wilcoxon signed rank sum test.

Med, Median; IQR, Interquartile Range; TRAM, transverse rectus abdominis muscle.

* Comparisons were made for Adjuvant Therapy vs No Adjuvant Therapy for the Breast Conserving Therapy module only.

† Comparisons were made for Implant Reconstruction vs TRAM Reconstruction for the Breast Reconstruction module only.