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ORIGINAL ARTICLE – BREAST ONCOLOGY

Clinical Validation of the BREAST-Q Breast-Conserving Therapy Module

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ABSTRACT

Background. The BREAST-Q is a patient-reported outcome measure to evaluate satisfaction and health-related quality of life (HRQOL) after breast surgery. The aim of this study is to test the acceptability, reliability, and validity of the most recently developed BREAST-Q module for breast-conserving therapy (BCT) in a prospective clinical cohort.

Methods. The BREAST-Q BCT module was translated into German according to international guidelines. A total of 253 women with primary breast cancer undergoing BCT were recruited preoperatively. This study evaluated the BREAST-Q BCT subscales by using psychometric methods including acceptability, reliability, and validity. To examine construct validity, convergent and discriminant validity were determined by testing the instrument's scales against the EORTC C30 and BR23 as reference questionnaires.

Results. Acceptability was supported by a high follow-up rate (90%) and low frequency of missing data (< 10%) in all but three scales. Scale reliability was supported by high Cronbach's alpha coefficients (> 0.86) and item-total correlations (range of means, 0.33–0.89). Validity was shown by convergent and divergent correlations. The hypotheses of relationships between the scales of the BREAST-Q and the EORTC QLQ C30 BR23 revealed moderate to high correlations.

Conclusions. The BREAST-Q BCT module proved to be an accepted, reliable, and valid questionnaire for the assessment of HRQOL and patient satisfaction after BCT in breast cancer patients. It can be recommended as a possible standard PROM for individual clinical analysis, quality assessment, and future trials.

Due to ongoing improvements in treatment methods for early breast cancer, overall survival and breast-cancer-specific survival have never been higher than they are today.[1] Nowadays, long-term disease-free survival can be achieved in 80–90% of patients with primary breast cancer,[2] so the assessment of therapy should also include HRQOL.[3] In breast cancer surgery, breast conservation can be achieved in over 70% of women, and this has already been shown to result in higher HRQOL compared with mastectomy and similar HRQOL compared with mastectomy with reconstruction.[4,5] For breast-conserving therapy (BCT), correlations could be found between various esthetic and functional aspects (e.g., mobility, pain) and various factors of quality of life[5–8] e.g., self-esteem and self-concept.[9] Nonetheless, in BCT, the surgical methods (e.g. type of incision, resection, and reconstruction) may still differ considerably and therefore have different effects on HRQOL outcomes and patient satisfaction.

The use of patient-reported outcome measures (PROMs) has become an important method to collect information about the impact of breast cancer treatment on HRQOL.[10,11] Esthetic and functional outcomes are highly subjective attributes, and their evaluation may differ

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widely among individuals. Thus, high importance is being given to standardization of PROMs used to assess these attributes.[12,13] While various PROMs (designed by utilizing classical test theory) are being utilized in international *research*, (strictly speaking) only those designed in accord with the Rasch measurement method are applicable for use in *clinical practice*, e.g., to assess the patient's health status prior to treatment and to support clinical decision-making.[14,15]

The BREAST-Q is a breast-surgery-specific PROM that was developed in adherence with international guidelines for PRO instruments[16,17] to assess patients' satisfaction, HRQOL, and experience of care.[18] The BCT module is the latest module to be analyzed psychometrically and has been evaluated only in retrospective and cross-sectional studies so far, not prospectively.[19] By using the Rasch measurement method, the BREAST-Q gains an advantage over most other PROMs. The Rasch measurement method offers the ability to generate linear measurements from original-level data, whereas classical test theory—so far the prevalent psychometric scheme in PROM development—only provides ordinal measurements.[20] Thus, the BREAST-Q qualifies for enabling estimates not only for use in research and performance measures, but also for individual patient analyses in clinical practice with support in clinical decision-making.[20,21]

For the BREAST-Q BCT module to be used appropriately, it is important that its validity be demonstrated. The aim of this study is to prospectively utilize the BREAST-Q BCT module and evaluate its psychometric properties.

METHODS

Development of the German Version of the BREAST-Q BCT Module

The German version of the BREAST-Q BCT module (version 2.0) was translated according to the linguistic validation guidelines of the Mapi Research Trust.[22] Permission to proceed with this project was obtained from the Mapi Research Trust in 2016. The linguistic validation process requires two independent forward translations, a backward translation, and patient testing. The German version of the BREAST-Q BCT module that we developed is now accessible to the public from the homepage of the Mapi Research Trust.

Study Sample

Women who underwent BCT were recruited to participate in this study at the Women's Clinic of the University Hospital of Heidelberg from July 2017 through May 2018. The patients were included if they had a definite diagnosis of breast cancer, understood German, and were undergoing BCT. Patients were excluded if they had a diagnosis of recurrence or metastasis or declined to participate in the study.

The patients were informed about the study 1 day to 1 week prior to the surgery. If they agreed to participate, they completed the BREAST-Q preoperative BCT module and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires Cancer30 and Breast23 (EORTC QLQ-C30 and -BR23). One week after their surgery, the patients were sent the BREAST-Q postoperative BCT module and the EORTC QLQ-C30 and -BR23, along with a letter asking the patient to complete the questionnaires before the beginning of their radiation treatment. In this way, we tried to avoid the impact of radiotherapy side effects on patients' HRQOL.

BREAST-Q BCT Module

The BCT module of the BREAST-Q aims to examine patient satisfaction and HRQOL after breast-conserving therapy. The BCT preoperative module compromises four subscales with 30 items. As the patients were supposed to complete the postoperative questionnaire with its 9 subscales and 74 items after their surgery but before the radiotherapy, the subscale concerning the adverse effects of radiation was not administered in this study. Scores were computed for each of the questionnaire domains. These were transformed onto a scale of 0–100 according to the BREAST-Q protocol, with a higher value representing a more favorable outcome. Each scale of the BREAST-Q can be used independently of the other scales, and there is no overall or total BREAST-Q score.

EORTC Quality-of-Life Questionnaire

The EORTC QLQ C30 and BR23 questionnaires are well-established instruments and are considered to reliably measure HRQOL among cancer patients.[23–25] They were used here to test the construct validity of the BREAST-Q.

Statistical Analysis

Descriptive statistics included the mean/standard deviation and median/interquartile range for parametric and nonparametric data. The psychometric analysis included the evaluation of the acceptability, reliability, and construct validity. For the acceptability, the distribution of scores and rates of missing responses were examined. For the reliability, this study assessed the internal consistency using Cronbach's alpha coefficients (> 0.70) and item-total correlation (> 0.3). To examine construct validity, convergent

TABLE 1 Preoperative questionnaire: Item frequency distribution and missing percentage (%) ($N = 253$)

Subscale item	Response category					Missing	Subscale item	Response category					Missing
	1	2	3	4	5			1	2	3	4	5	
Satisfaction with breast							Physical well-being						
1a	1.2	9.1	56.5	32.4	–	0.8	3a	2.4	43.1	51.4	–	–	3.2
1b	3.6	13.0	49.8	31.6	–	2.0	3b	2.8	21.7	73.9	–	–	1.6
1c	5.5	21.7	44.7	25.7	–	2.4	3c	2.8	22.5	72.3	–	–	2.4
1d	7.9	23.4	51.0	16.2	–	1.2	3d	1.2	37.5	59.3	–	–	2.0
							3e	2.0	45.8	49.8	–	–	2.4
Psychosocial well-being							3f	2.4	45.1	49.4	–	–	3.2
2a	0	4.0	10.3	43.9	39.1	2.8	3 g	5.1	31.6	60.9	–	–	2.4
2b	0.8	5.1	11.1	43.1	37.2	2.8	3 h	0.4	26.5	70.8	–	–	2.4
2c	1.2	8.3	12.6	42.7	32.0	3.2	3i	1.6	29.2	66.8	–	–	2.4
2d	0.4	6.3	9.9	37.9	43.1	2.4	3j	0.4	13.8	83.4	–	–	2.4
2e	0	5.5	12.3	41.1	37.5	3.6							
2f	0.4	3.6	12.3	38.3	42.3	3.2	Sexual well-being						
2 g	0.7	3.6	12.6	43.5	37.2	2.4	4a	3.2	8.7	22.1	42.7	12.6	10.7
2 h	1.2	4.0	11.9	38.3	39.5	5.1	4b	3.6	7.9	15.0	40.7	16.2	16.6
2i	0.8	4.0	13.8	39.5	36.8	5.1	4c	4.3	7.5	16.6	38.3	19.4	13.8
2j	1.6	9.5	19.4	41.1	24.5	4.0	4d	3.6	7.1	15.4	37.9	20.2	15.8
							4e	5.1	5.9	12.3	38.7	24.5	13.4
							4f	8.6	10.9	20.2	36.0	14.2	12.6

and discriminant validity were determined by testing the BREAST-Q scales against the validated EORTC C30 and BR23 as a reference questionnaire measuring related aspects, using a multitrait–multimethod approach (MMTM). Cohen's guidelines for the interpretation of correlation coefficients were used: correlations between 0.50 and 1.00 were interpreted as strong, correlations between 0.30 and 0.50 as moderate, correlations between 0.10 and 0.30 as weak, and correlations < 0.10 as very weak.[26]

We hypothesized the following: BREAST-Q's psychosocial well-being scale and EORTC's social function, role function, emotional function, and cognitive function scales would exhibit moderate to high correlations, as they all measure factors contributing to a patient's well-being on a psychological, nonphysical level. Moreover, we assumed that the physical well-being scale would have a negative correlation with the breast symptom and arm symptom scales, because this scale contains items concerning pain and morbidity in arms and breast. Furthermore, we hypothesized that the EORTC's symptom scales fatigue and pain would also have a negative correlation with the physical well-being scale. The BR23's body image scale was expected to correlate with the satisfaction with breast subscale. The sexual well-being scale of the BREAST-Q was expected to correlate with the sexual functioning and sexual enjoyment items of the EORTC questionnaire due to the similar topic.

The data were analyzed using SPSS software, version 24 (IBM; Armonk, NY, USA).

RESULTS

All reports of the linguistic validation process and the final translated versions were sent to the Mapi Research Trust and accepted, thus the German version of the BREAST-Q BCT module that we developed is now open to the public. It is available from the Mapi Research Trust and can be accessed from their homepage.

Patient Characteristics

Between July 2017 and May 2018, 259 patients were recruited to participate in this study. Five patients were excluded because they opted for mastectomy instead of BCT as surgical therapy, and one patient was unable to fill out the questionnaire because of language problems. Thus, 253 patients completed the preoperative questionnaire. The postoperative BREAST-Q questionnaire was sent to this cohort of 253 patients 1 week after surgery. The postoperative questionnaire was returned by 219 (90%) of the 253

TABLE 2 Postoperative questionnaire: Item frequency distribution and missing percentage (%) (N = 219)

Subscale item	Response category					Missing	Subscale item	Response category					Missing
	1	2	3	4	5			1	2	3	4	5	
Satisfaction with breast							*Satisfaction with information*						
1a	1.4	7.8	49.8	38.8	–	2.3	5a	4.6	7.3	52.1	25.6	–	10.5
1b	1.8	5.5	48.4	42.9	–	1.4	5b	4.6	6.8	46.1	35.2	–	7.3
1c	1.8	4.6	45.2	47.5	–	0.9	5c	5.0	14.2	42.5	26.5	–	11.9
1d	2.3	17.8	47.9	27.9	–	4.1	5d	4.6	18.3	44.7	23.7	–	8.7
1e	3.2	9.6	56.2	29.2	–	1.8	5e	8.2	21.0	37.0	14.6	–	19.2
1f	1.4	14.6	53.4	29.2	–	1.4	5f	4.6	25.1	39.7	18.7	–	11.9
1g	0.9	14.6	52.5	28.8	–	3.2	5g	4.1	12.8	44.3	28.3	–	10.5
1h	3.2	14.6	51.1	28.8	–	2.3	5h	9.6	21.9	35.6	19.2	–	13.7
1i	1.4	14.2	53.0	29.7	–	1.8	5i	6.4	17.8	44.7	21.5	–	9.6
1j	3.7	18.3	50.2	25.6	–	2.3	5j	6.4	22.8	40.2	20.1	–	10.5
1k	3.2	21.0	53.9	20.1	–	1.8	5k	6.8	21.0	41.1	21.5	–	9.6
							5l	7.3	21.0	40.6	21.0	–	10.0
Psychosocial well-being													
2a	0.5	2.7	9.1	39.7	45.7	2.3	*Satisfaction with surgeon*						
2b	0	5.9	14.6	47.5	30.1	1.8	6a	0.5	2.3	22.8	61.6	–	12.8
2c	0.5	7.8	16.0	46.6	26.9	2.3	6b	4.6	5.9	22.8	52.5	–	14.2
2d	0.5	5.0	13.7	35.6	43.3	1.8	6c	6.4	17.4	26.0	34.7	–	15.5
2e	0	5.0	15.5	35.6	42.0	1.8	6d	5.0	11.0	26.5	41.6	–	16.0
2f	0.5	4.1	16.0	34.2	43.4	1.8	6e	5.0	8.2	26.5	46.6	–	13.7
2g	0.5	4.1	12.8	41.6	38.8	2.3	6f	5.0	8.7	31.1	40.2	–	15.1
2h	0.9	5.5	11.4	43.8	35.2	3.2	6g	0.5	4.1	26.5	54.8	–	14.2
2i	0.5	7.3	12.3	40.6	36.5	2.7	6h	7.8	8.2	26.0	43.4	–	14.6
2j	1.8	9.1	21.9	39.7	23.7	3.7	6i	4.1	6.8	25.1	46.1	–	17.8
							6j	4.6	6.4	26.9	46.1	–	16.0
Physical well-being							6k	5.5	8.2	28.8	42.0	–	15.5
3a	20.5	56.6	21.5	–	–	1.4	6l	9.1	13.2	27.4	30.6	–	19.6
3b	13.2	58.0	27.9	–	–	0.9							
3c	19.4	60.8	19.8	–	–	0.9	*Satisfaction with medical team*						
3d	15.1	69.9	14.2	–	–	0.9	7a	0	1.8	24.7	70.3	–	3.2
3e	24.7	61.6	12.8	–	–	0.9	7b	0	1.4	18.7	77.6	–	2.3
3f	9.1	48.9	41.1	–	–	0.9	7c	0	1.8	26.5	68.9	–	2.7
3g	11.9	56.6	30.1	–	–	1.4	7d	0	0.5	16.4	79.9	–	3.2
3h	17.4	42.0	38.8	–	–	1.8	7e	0.5	3.7	18.3	74.0	–	3.7
3i	67.1	20.1	11.9	–	–	0.9	7f	0.5	4.6	20.5	71.7	–	2.7
							7g	1.8	6.8	22.8	65.8	–	2.7
Sexual well-being													
4a	2.7	7.3	23.3	41.6	15.1	10.0	*Satisfaction with office staff*						
4b	10.0	13.2	16.0	35.6	6.4	18.7	8a	0	2.3	29.2	65.8	–	2.7
4c	7.8	13.2	18.3	35.6	9.1	16.0	8b	0	2.7	21.0	74.4	–	1.8
4d	8.2	11.4	14.2	34.2	12.8	19.2	8c	0	3.2	33.3	59.4	–	4.1
4e	7.3	13.7	19.6	27.9	15.1	16.4	8d	0	1.8	24.2	72.1	–	1.8
4f	5.5	19.6	20.5	27.4	10.5	16.4	8e	0.5	6.4	24.7	66.2	–	2.3
							8f	0.5	1.4	32.0	63.5	–	2.7
							8g	0.5	7.3	25.6	64.4	–	2.3

patients. The mean (SD) age of the cohort was 57.8 (11.03) years.

Psychometric Analysis: Acceptability

The item frequency distribution and rates of missing responses for each item during the first administration are presented in Table 1 (preoperative) and Table 2 (postoperative). The acceptability was lowest in the "sexual well-being" subscale [mean of missing rates 13.8% (preoperative) and 16.1% (postoperative)] and in the "satisfaction with surgeon" subscale (mean of missing rates 16.4%). There were also high rates of missing responses on the subscale "satisfaction with information" (mean of missing rates 11.1%). Ceiling or floor effects did not occur.

Psychometric Analysis: Reliability

The internal consistency of all of the questionnaire's scales was strong, with Cronbach's alpha ranging between 0.86 and 0.97. Furthermore, the item-total correlations were high, with 0.33 being the exceptionally lowest score of an item of the physical well-being scale (Table 3).

Psychometric Analysis: Construct Validity

The results of the convergent and divergent validity are presented in Table 4 (preoperative) and Table 5 (postoperative). The BREAST-Q psychological well-being scale and most C30 functional scales, i.e., emotional functioning, cognitive functioning, and social functioning, showed statistically significant moderate to high correlations (0.41 to 0.55) in both preoperative and postoperative questionnaires. The physical well-being scale correlated moderately negatively with the fatigue and arm symptoms scales (− 0.56 to − 0.38) and highly negatively with the pain and breast symptom scales (− 0.72 to − 0.52). Furthermore, the psychosocial and physical well-being scales showed moderate to high correlations (0.36 and 055) with the C30 quality-of-life scale. The correlations of the sexuality scales did not meet our hypothesis: The sexual well-being and the sexual functioning scale's correlations were unexpectantly negative (− 0.46 to − 0.30), and the sexual enjoyment scale's correlation was highly negative (− 0.60 to − 0.49). The sexual functioning and sexual enjoyment scales also had low correlations with the other scales of the BREAST-Q. As expected, the satisfaction with breast scale showed its highest correlation with the body image scale, with a moderate correlation of 0.44 in the pre- and 0.49 in the postoperative questionnaire. The analysis indicated generally higher correlations between the BREAST-Q domains and the EORTC C30 and BR28 scales in the postoperative questionnaires than the preoperative questionnaires.

DISCUSSION

The necessity of considering the use of PROMs as important end-points and as tools for quality control is well established. It is also especially important for breast cancer patients, because they have several different surgical treatment options with identically high survival rates but variable impact on individual patient HRQOL.[21,27,28] PROMs can be used to educate patients and help to guide the decision-making process. Nevertheless, PROMs such as the BREAST-Q are not routinely used to account for patient satisfaction and HRQOL in breast cancer treatment, although the association between esthetic, functional, and

TABLE 3 Internal consistency

Subscales	Preoperative				Postoperative			
	No. of items	*N*	Cronbach's α	Item-total correlation range	No. of items	*N*	Cronbach's α	Item-total correlation range
Satisfaction with breast	4	243	0.86	0.59–0.76	11	201	0.95	0.67–0.82
Psychosocial well-being	10	225	0.94	0.68–0.80	10	201	0.95	0.69–0.86
Physical well-being	10	238	0.88	0.40–0.76	9	207	0.86	0.33–0.70
Sexual well-being	6	200	0.92	0.69–0.83	6	173	0.94	0.76–0.89
Satisfaction with information	–	–	–	–	12	159	0.96	0.65–0.85
Satisfaction with surgeon	–	–	–	–	12	156	0.97	0.72–0.89
Satisfaction with medical team	–	–	–	–	7	207	0.92	0.74–0.79
Satisfaction with office staff	–	–	–	–	7	208	0.95	0.78–0.85

TABLE 4 Convergent and discriminant validity (Spearman's rho), preoperative questionnaire

Scale/item	BREAST-Q			
	Satisfaction with breast	Psychosocial well-being	Physical well-being	Sexual well-being
EORTC QLQ C30				
Physical functioning	0.29**	0.24**	0.31**	0.23**
Role functioning	0.14*	0.30**	0.32**	0.20**
Emotional functioning	0.28**	0.51**	0.38**	0.30**
Cognitive functioning	0.31**	0.42**	0.34**	0.28**
Social functioning	0.25**	0.41**	0.33**	0.23**
Fatigue	− 0.31**	− 0.33**	− 0.38**	− 0.21**
Pain	− 0.17**	− 0.20**	− 0.52**	− 0.14*
Quality of life	0.39**	0.55**	0.36**	0.40**
EORTC QLQ BR23				
Body image	0.44**	0.53**	0.15*	0.52**
Sexual functioning	− 0.07	− 0.16*	− 0.06	− 0.30**
Sexual enjoyment	− 0.22*	− 0.27**	0.11	− 0.49**
Future perspective	0.30**	0.34**	0.28**	0.20**
Breast symptoms	− 0.19**	− 0.19**	− 0.71**	− 0.03
Arm symptoms	− 0.15*	− 0.15*	− 0.41**	− 0.07

EORTC European Organisation for Research and Treatment of Cancer, *QLQ* Quality of life Questionnaire, *C30 Cancer30*, *BR23* Breast23
*$p < .05$, **$p < .01$

psychological outcomes with higher HRQOL has already been shown.[29,30] Body image issues may have a major impact on a cancer patient's psychosocial well-being and thus HRQOL.[31,32] A woman's breasts have special significance in this context as they are, different from most other body parts, associated with female identity, sexuality, and self-esteem, and pronounced breast asymmetry after breast cancer surgery is significantly correlated with poor psychosocial functioning.[33] Studies have shown that the psychological impact of losing her breast is one of the reasons for a woman to choose BCT over mastectomy if surgically indicated.[34] Furthermore, it has been shown that the baseline status of a patient's social functioning acts as a prognostic measure of survival beyond a number of biomedical parameters previously known in other types of cancer,[35] suggesting that this might also be true for breast cancer. It has also been shown that patient satisfaction with service quality can be an independent predictor of survival in breast cancer.[36]

An internationally agreed standard instrument is necessary in order to conduct and properly compare prospective studies on the various surgical techniques and their outcomes. Our study provides evidence that the BREAST-Q is a valid PROM that meets these needs.[18] In this validation study, we preoperatively included all patients undergoing BCT at our clinic with a high follow-up rate of 90% in the postoperative assessment. Thus, we were able to evaluate a representative cohort of breast cancer patients treated in the everyday clinical routine and reduce a possible selection bias.

Like the other modules of the BREAST-Q, the BCT module has the advantage of having separate preoperative and postoperative questionnaires, designed specifically to document changes from the baseline status.[37] Its many therapy-specific modules all have the same underlying concept and scoring system, making the different modules and their results comparable with each other. By using the Rasch measurement method in its scoring system, it generates high-quality data suited not only for research but also for individual patient analyses in clinical practice,[20,38] thus standing out among other PRO instruments for the assessment of HRQOL.[12]

Our findings show the ability of the BREAST-Q BCT questionnaire to assess precisely those impacts of breast surgery that matter to the patients. In addition to correlating with many psychological functioning scales of the EORTC C30, the psychosocial well-being scale of the BREAST-Q BCT correlates highly with the C30's "quality of life" scale and the BR23's "body image" scale. This suggests that the aspects of psychosocial well-being upon which the body image has great impact are assessed by the BREAST-Q. In contrast, the negative correlations of the psychosocial

TABLE 5 Convergent and discriminant validity (Spearman's rho), postoperative questionnaire

Scale/item	BREAST-Q							
	Satisfaction with breast	Psycho-social well-being	Physical well-being	Sexual well-being	Satisfaction with information	Satisfaction with surgeon	Satisfaction with medical team	Satisfaction with office staff
EORTC QLQ C30								
PF	0.30**	0.38**	0.55**	0.38**	0.30**	0.16*	0.21**	0.19**
RF	0.29**	0.36**	0.55**	0.27**	0.24**	0.14	0.16*	0.13
EF	0.34**	0.58**	0.43**	0.46**	0.34**	0.35**	0.25**	0.26**
CF	0.27**	0.42**	0.33**	0.41**	0.34**	0.24**	0.19**	0.16*
SF	0.30**	0.49**	0.52**	0.51**	0.39**	0.24**	0.23**	0.25**
FA	− 0.26**	− 0.43**	− 0.56**	− 0.42**	− 0.29**	− 0.18*	− 0.25**	− 0.19**
PA	− 0.18**	− 0.33**	− 0.72**	− 0.27**	− 0.29**	− 0.10	− 0.09	− 0.10
QL	0.35**	0.53**	0.53**	0.45**	0.39**	0.31**	0.29**	0.27**
EORTC QLQ BR23								
BI	0.49**	0.72**	0.31**	0.67**	0.26**	0.26**	0.20**	0.27**
SEF	− 0.16*	− 0.21**	− 0.16*	− 0.46**	− 0.19*	− 0.09	− 0.08	− 0.13
SEE	− 0.33**	− 0.35**	− 0.35**	− 0.60**	− 0.28*	− 0.13	− 0.15	− 0.14
FU	0.30**	0.43**	0.33**	0.34**	0.29**	0.23**	0.19**	0.17*
BS	− 0.32**	− 0.42**	− 0.69**	− 0.41**	− 0.31**	− 0.18*	− 0.21**	− 0.14*
AS	− 0.15*	− 0.19**	− 0.53**	− 0.20**	− 0.25**	− 0.08	− 0.10	− 0.06

EORTC European Organisation for Research and Treatment of Cancer, *QLQ* quality of life questionnaire, *C30* Cancer30, *PF* physical functioning, *RF* role functioning, *EF* emotional functioning, *CF* cognitive functioning, *SF* social functioning, *FA* fatigue, *PA* pain, *QL* quality of life, *BR23* Breast23, *BI* body image, *SEF* sexual functioning, *SEE* sexual enjoyment, *FU* future perspective, *BS* breast symptoms, *AS* arm symptoms

*$p < .05$, **$p < .01$

well-being scale and the physical symptom scales of the C30 are moderate at most (− 0.35 to − 0.13). Thus, the BREAST-Q shows that the HRQOL of breast cancer patients depends highly on the self-perception of their body and its psychosocial consequences and less on their actual physical symptoms.

The construct validity of most scales was confirmed through correlation with the well-established EORTC questionnaires. Only the sexual well-being scale did not show the hypothesized correlations. Upon further examination of this scale in comparison with the related items of the EORTC BR23, one may notice that the scales only seem to correspond at first glance. While the BR23 questions ask about sexual *activity* and the enjoyment of it, the BREAST-Q emphasizes the patient's self-assessment of sexual *attractivity*. So, the BREAST-Q again focuses on assessing the surgery's impact on body image and inner psychological perceptions. As this explanation is only a data-derived hypothesis, it represents an area for further evaluations in the future.

One weakness of the BCT module might be its total number of 74 questions, making the questionnaire comparatively long. This potential disadvantage was also mentioned in the patient interviews during the linguistic validation process. Despite the length, the feasibility of the BREAST-Q reconstruction module (which has a similar length to the BCT module) was demonstrated by its usage in several large-scale studies such as the National Health Service audit on mastectomy and breast reconstruction with data from over 8000 patients and a response rate of 81%.[27] Nonetheless, a shorter version of the BREAST-Q BCT would make it easier and more practical to use this questionnaire in research studies and routine clinical care.

In conclusion, the results of this study prove that the BREAST-Q BCT module is an accepted, reliable, and valid questionnaire for HRQOL research after BCT in breast cancer patients. The usage of the BREAST-Q in recent years has already delivered meaningful data that may serve as a benchmark for future investigations.[19] Together, these factors enable the recommendation of the BCT module as a possible standard PROM for clinical practice, for quality assessment, and in clinical research trials.

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ETHICAL APPROVAL The study was approved by the ethics commission of the University of Heidelberg Medical School. The study was deemed to be without risk, including only anonymized analysis of routinely collected data; consequently the ethics committee of the University of Heidelberg did not request approval for consent for this analysis.

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