



Psychometric validation of the Breast Cancer Treatment Outcome Scale (BCTOS-12): a prospective cohort study

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Abstract

Purpose The Breast Cancer Treatment Outcome Scale (BCTOS) is a questionnaire to evaluate the aesthetic and functional outcome after breast conserving surgery (BCS). The original BCTOS with its 22 items on three subscales was refined to a shorter, improved, and easier to administer patient-reported outcome measure, the BCTOS-12. The BCTOS-12 consists of 12 items on two distinct subscales, the Functional Status and the Aesthetic Status. The aim of this study was to validate the BCTOS-12 in a prospective cohort.

Methods For this study, 239 breast cancer patients were included preoperatively, and 204 patients completed the BCTOS-12 and EORTC QLQ C30 BR23 shortly after their BCS, corresponding to a follow-up rate of 85%. The item-factor structure was examined by confirmatory factor analysis. The reliability was calculated by McDonald's Omega for estimating internal consistency. The convergent validity was assessed by Spearman's rank correlation coefficients between the related scales of the questionnaires.

Results The BCTOS-12 showed a robust item-factor structure and a good internal consistency with McDonald's Omega of 0.89 for the Aesthetic Status and 0.90 for the Functional Status. A high convergent and divergent validity was indicated by correlations between the subscales of the EORTC QLQ C30 BR23 and the BCTOS-12.

Conclusion Overall, the results demonstrate a successful psychometric validation of the BCTOS-12. The BCTOS-12 is a refined, improved, and now validated, instrument. It can be used in clinical studies and routine management for the evaluation of the aesthetic and functional outcome after BCS.

Keywords Breast Cancer Treatment Outcome Scale · BCTOS-12 · Breast conserving surgery · Aesthetic and functional result · Patient-reported outcomes · Quality of life

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Purpose

Breast cancer is the most common malignancy in women and comprises the largest group of cancer survivors. Due to ongoing improvements of the treatment methods for early-stage breast cancer, the overall survival with 90.5% and breast cancer-specific survival with up to 95% after 5 years have never been higher than they are today [1, 2]. However, the prevalence of psychological distress is common in this patient population. Psychosocial outcomes, such as postoperative quality of life (QoL), are increasingly valuable outcome information in addition to the classical oncological end-points [3–7].

In breast cancer surgery, patient postoperative QoL is influenced by the aesthetic and functional outcome of the surgery [5, 8]. Breast conservation surgery (BCS) is accepted as the standard treatment for early-stage breast cancer, although the aesthetic and functional outcomes vary widely [9–11]. Various resection, incision, and reconstruction methods are used to improve the aesthetic and functional outcomes after BCS, thus aiming to achieve better QoL. A substantial number of patients report an unfavorable aesthetic and functional outcome with a decreased QoL after BCS [12–19]. Although evaluation of the aesthetic and functional outcomes is necessary, a comprehensive and easy-to-administer patient-reported outcome tool is still lacking. Patient-reported outcome measures (PROMs) to evaluate the aesthetic and functional results range from single questions of overall assessment to extensive questionnaires that try to involve different aspects of the surgical outcome. Among others, specific surgical sequelae with respect to breast size, breast shape, scars, arm pain, and shoulder movement are of interest.

Among the frequently used assessment tools, the Breast Cancer Treatment Outcome Scale (BCTOS) [20] is one of the most clearly structured and comprehensive PROMs. It addresses the most important dimensions of after-treatment morbidity with respect to aesthetic and functional results. In its original version by Stanton et al., the BCTOS comprises 22 items (BCTOS-22) on three subscales assessing the Cosmetic Status, the Functional Status, and the Breast-specific pain [20]. The third subscale, the Breast-specific pain, may be viewed as a further aspect of the Functional Status and therefore provides only a minor gain in additional information. Furthermore, this specific subscale was seldom analyzed in clinical research [17, 21, 22]. Moreover, several of the other 22 individual items of the BCTOS seem to be redundant and may not contribute to better differentiation between favorable and unfavorable surgical outcomes.

We propose a shortened and refined version of the BCTOS questionnaire by reducing the number of items

and subscales—the BCTOS-12 [23]. This new version of the BCTOS questionnaire consists of 12 items on two distinct subscales, the new Aesthetic Status and the new Functional Status. The BCTOS-12 is easier to administer and to interpret, but its psychometric properties were based on an existing data set assessing the patient-reported outcomes with the original BCTOS-22. Therefore, validation with a prospectively collected data set using the BCTOS-12 was still needed. Here we report the results of a validation study of the BCTOS-12, with an examination of the robustness of the item-factor structure, evaluating the reliability and the validity of the questionnaire.

Methods

Study sample

This psychometric validation of the BCTOS-12 questionnaire is based on a prospectively acquired data set of 204 patients who underwent BCS between 27 June 2017 and 27 August 2018. Patients were included in the study if they had a definite diagnosis of breast cancer, were able to read German, and had an ECOG performance status < 2. Patients with and without a primary systemic therapy were eligible for study participation. Patients were excluded if they had a local recurrence or distant metastasis.

The patients were informed and screened for study participation 1 week to 1 day before their BCS. One week after surgery, they were sent the BCTOS-12 and European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires Cancer30 and Breast23 (EORTC QLQ C30 B23). Thus, the questionnaires were completed 1–4 weeks after surgery. The study was approved by the Ethics Commission of the Medical School of the University of Heidelberg. All patients provided written informed consent.

The Breast Cancer Treatment Outcome Scale (BCTOS)

The BCTOS was designed to assess women's subjective evaluation of both the aesthetic and functional outcomes after BCS [20]. The original questionnaire comprised 22 items, which were assigned to three internally consistent subscales: (1) Functional Status, (2) Aesthetic Status, and (3) Breast Sensitivity Status. Based on an existing data set of 871 patients, we reduced the BCTOS to 12 items on two subscales (Table 1) [23]. The new Functional Status comprises four items: (1) “arm heaviness”, (2) “shoulder discomfort”, (3) “arm discomfort”, (4) “arm swelling”, and

Table 1 Breast Cancer Treatment Outcome Scale (BCTOS-12)

	1 No differ- ence	2	3	4 Large differ- ence
1. Breast shape	1	2	3	4
2. Breast texture	1	2	3	4
3. Arm heaviness	1	2	3	4
4. Nipple appearance	1	2	3	4
5. Shoulder discomfort	1	2	3	4
6. Arm discomfort	1	2	3	4
7. Breast tenderness	1	2	3	4
8. Scar tissue	1	2	3	4
9. Arm swelling	1	2	3	4
10. Breast swelling	1	2	3	4
11. Fit of bra	1	2	3	4
12. Breast sensitivity	1	2	3	4

The BCTOS-12 consists of 12 items with two distinct subscales: Aesthetic Status and Functional Status. Patients are instructed to rate each item on a four-point scale evaluating the difference between treated and untreated breast (1 = no difference to 4 = large difference)

the new Aesthetic Status comprises eight items: (1) “breast shape”, (2) “breast texture”, (3) “nipple appearance”, (4) “breast tenderness”, (5) “scar tissue”, (6) “breast swelling”, (7) “fit of bra”, and (8) “breast sensitivity”.

Patients are instructed to rate each item of the BCTOS questionnaire on a four-point rating scale evaluating the differences between the treated and untreated breast (1 = no difference to 4 = large difference). The score for each subscale is calculated as the mean of its items, with the score ranging from 1.00 to 4.00. A higher score reflects a poorer status.

The EORTC QLQ C30 BR23 questionnaire

The EORTC QLQ C30 BR23 is a widely used QoL instrument for cancer patients, which has been validated according to the requirements of the EORTC [24] in several languages [25], including German [26]. This questionnaire consists of a general module, the QLQ-C30, and a breast cancer-specific module, the QLQ-BR23. The QLQ-C30 includes 30 items with 15 subscales; whereas, the QLQ-BR23 comprises 23 items in 8 subscales. The resulting scores for each subscale range from 0 to 100, with a higher score indicating a higher prevalence. For example, a high score for the global health status represents a high QoL, whereas a high score for a symptom scale represents a high level of symptoms. A recently published and validated global summary score comprising all existing scales of the QLQ-C30 [27] was also used in our study.

Statistical analysis

The study population was characterized using descriptive measures of the empirical distributions. The factor structure of the BCTOS-12 was verified by confirmatory higher order factor analysis models considering the respective model fit [28], represented by the root mean square mean error of approximation (RMSEA), the comparative fit index (CFI), and the Tucker–Lewis index (TLI). These model fit parameters are typically used in confirmatory factor analysis [29] to describe the difference between the observed and estimated model. A good model fit is indicated by a small (close to 0) RMSEA and large (close to 1) CFI and TLI.

Reliability was examined by assessing the internal consistency. Internal consistency is the extent to which items comprising the subscale measure the same concept. It was examined by McDonald’s Omega based on polychoric correlations.

The validity of the BCTOS-12 was evaluated by assessing the construct validity. The concept of construct validity indicates whether an instrument measures the construct that it is supposed to measure in an adequate way. This was performed by calculating the convergent and divergent validity, i.e., examining the relationship to another questionnaire that is used for the assessment of similar outcomes in breast cancer patients. Therefore, we compared the subscales of the BCTOS-12 with the validated scales from the EORTC QLQ C30 & BR23 questionnaire by Spearman’s rank correlation coefficients.

We hypothesized that the Functional Status of the BCTOS would be correlated to the “physical functional” scale of the EORTC QLQ C30 and to the “arm symptoms” scale of the BR23, as they measure similar surgical outcomes. We also assumed a correlation between the Aesthetic Status of the BCTOS and the “body image” scale and the “breast symptoms” scale of the EORTC QLQ BR23. In addition, we hypothesized that both the Aesthetic and Functional Status would correlate with the “global health status” and the C30 summary score, reflecting the influence on both BCTOS subscales on overall QoL.

All statistical calculations were performed with the “psych” package [30] and the “lavaan” package [31] of the statistic software R, version 3.5.1 [32].

Results

Patient characteristics

Altogether, 239 patients fulfilled the study criteria and were included in the study before their surgery, and 204 patients returned the questionnaires which correspond to a high participation rate of 85%. The median (Q1–Q3) age of the

study population was 57 (50–65) years, and the range was 30–82. The majority of patients had a breast size of cup A/B (54.1%), a tumor size less than 2 cm (69.6%), and were diagnosed with infiltrating ductal carcinoma (79.4%). Patient characteristics were collected from their medical record and are summarized in Table 2.

Item-factor structure

Methods of confirmatory factor analysis were used: since the two factors (Aesthetic Status and Functional Status) of the BCTOS-12 showed moderately high correlation (0.54), a higher order bifactor model was performed and the model fit was examined. An RMSEA of 0.083, a CFI of 0.987, and a TLI of 0.979 were obtained. These results all indicate a good model fit, confirming the two-dimensional item-factor structure of the BCTOS-12.

Reliability

The McDonald's Omega was 0.89 for the Aesthetic Status and 0.90 for the Functional Status, indicating very good internal consistency for both subscales. Since the subscales of the BCTOS-12 showed a moderate correlation, we also

considered the multidimensional McDonald's Omega coefficient, which confirmed the high reliability of the questionnaire (Omega total = 0.91, Omega hierarchical = 0.90).

Validity

To assess the convergent validity, we calculated Spearman's rank correlation coefficients between the subscales of the BCTOS-12 and the validated scales of the EORTC QLQ C30 BR23 (Table 3). The scales showed good convergent validity: e.g., the Aesthetic Status showed moderate correlation to the "body image" score (−0.45), and the Functional Status showed high correlations to the "arm symptoms" scale (0.76) and the "physical functioning" scale (−0.55). Furthermore, neither of the scales showed correlations to the "fatigue" scale (−0.01, 0.07; divergent validity). Additionally, high correlations with the "summary" score (Aesthetic Status −0.60, Functional Status −0.53) and the "global health status" (Aesthetic Status −0.53, Functional Status

Table 2 Characteristics of the study cohort

Variable	<i>n</i>	Percentage (%)
Age [years], median (Q1–Q3)	204	57 (50–65)
Breast size	204	
Cup A	14	9.7
Cup B	64	44.4
Cup C	35	24.3
> Cup C	31	21.5
Missings	60	29.4
Pathological T-stage	204	
(y)pTis	20	9.8
(y)pT0	23	11.3
(y)pT1a–1c	119	58.3
(y)pT2–4	42	20.6
Pathological N-stage	204	
(y)pN0	143	70.1
(y)pN+	45	22.1
No lymphonodectomy performed	16	7.8
Histological subtype	204	
Ductal carcinoma in situ	20	9.8
Invasive ductal carcinoma	162	79.4
Invasive lobular carcinoma	20	9.8
Others	2	1.0
Neoadjuvant therapy	204	
Yes	63	30.9
No	141	69.1

Table 3 Correlation coefficients (Spearman's rho) between the subscales of the BCTOS-12 and the subscales of the EORTC QLQ C30 BR23

EORTC scale	Aesthetic Status	Functional Status
QLQ C30 functional scales		
Physical functioning	−0.48	−0.55
Role functioning	−0.54	−0.47
Emotional functioning	−0.46	−0.33
Cognitive functioning	−0.31	−0.36
Social functioning	−0.47	−0.45
QLQ C30 symptom scales		
Fatigue	0.05	−0.01
Nausea and vomiting	0.2	0.2
Pain	0.53	0.55
Dyspnoea	0.19	0.31
Insomnia	0.42	0.2
Appetite loss	0.35	0.32
Constipation	0.23	0.19
Diarrhoea	0.06	0.03
Financial difficulties	0.25	0.31
QLQ C30 global health status	−0.56	−0.48
QLQ C30 summary score	−0.60	−0.53
QLQ BR23 scales		
Systematic therapy side effects	0.38	0.41
Upset by hair loss	0.1	0.11
Breast symptoms	0.71	0.48
Arm symptoms	0.41	0.77
Body image	−0.45	−0.31
Sexual functioning	−0.11	−0.15
Sexual enjoyment	−0.12	−0.22
Future perspective	−0.29	−0.27

–0.46) underline the important relationship of the two subscales of the BCTOS-12 to the patients' general QoL.

Score values and acceptability

The median (Q1–Q3) for the Aesthetic Status that we observed in our cohort was 2.00 (1.63–2.63). The median (Q1–Q3) for the Functional Status was 1.50 (1.00–2.25). The distribution of the scores can be found in Fig. 1.

The response patterns per item are presented in Table 4. None of the items was highly skewed, and all items except of item 8 (“scar tissue”) had very low rates of missing data (<3%). This indicates high acceptability of the questionnaire for the patients.

Discussion

In this study, we present a validated patient-reported outcome measure, the BCTOS-12. The psychometric properties of the questionnaire were examined on the basis of a prospectively collected patient cohort.

In BCS, various incision, resection, and reconstruction methods are used to try to improve the aesthetic and functional outcome. Several studies have shown that the aesthetic and functional outcomes of BCS have an influence on the patients' QoL [5, 8, 12–15]. In our study, high correlations of the aesthetic and functional scores of the BCTOS-12 with the “global health status” and the “summary score” of the EORTC QLQ C30 underline the importance and relevance of the aesthetic and functional aspects for patients' QoL. Yet a systematic evaluation

Table 4 Relative frequencies of the item response distributions (in %) and rate of missing answers (in %)

Item	1	2	3	4	Missing
1. Breast shape	24.4	51.7	18.4	5.5	1.5
2. Breast texture	24.4	33.8	28.8	13.1	2.9
3. Arm heaviness	43.0	33.5	15.5	8.0	1.9
4. Nipple appearance	46.0	33.3	14.6	6.1	1.5
5. Shoulder discomfort	56.7	25.9	10.9	6.5	2.9
6. Arm discomfort	43.1	29.7	14.9	12.4	1.0
7. Breast tenderness	14.4	45.3	24.9	15.4	1.5
8. Scar tissue	16.5	49.5	23.9	10.1	7.8
9. Arm swelling	65.0	24.5	5.0	5.5	1.9
10. Breast swelling	34.3	38.8	16.9	9.9	1.5
11. Fit of bra	45.0	39.0	11.0	5.0	1.9
12. Breast sensitivity	24.6	40.2	23.6	11.6	2.5

of the various surgical techniques and their influence on these outcomes is still not available. A prerequisite for such studies is a validated and easy-to-administer PROM.

The proposed BCTOS-12 is focused specifically on the aesthetic and functional outcome after BCS. The questionnaire comprises 12 items and assesses various aspects of patients' subjective perception of the surgical result. The first subscale, the Aesthetic Status, is composed of eight items referring to the breast. The second subscale, the Functional Status, is composed of four items referring to the arm and shoulder. This structure with two distinct subscales of the BCTOS-12 was confirmed in our study by confirmatory factor analysis showing a robust item-factor structure.

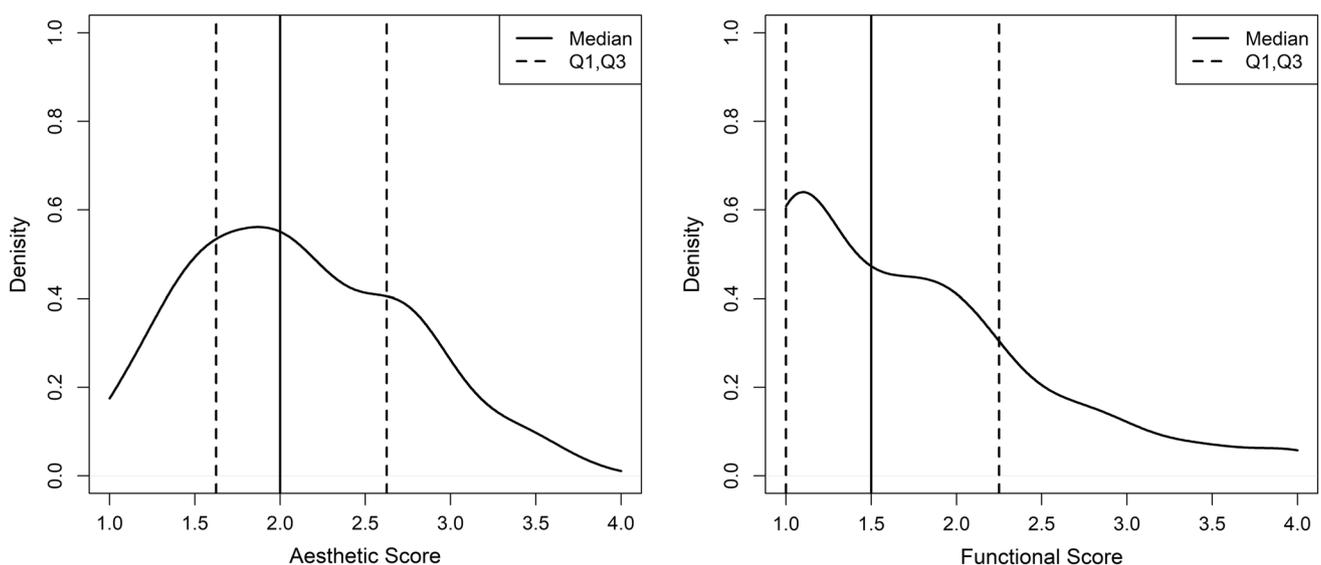


Fig. 1 Score distributions of the subscales of the BCTOS-12 in the validation cohort

In our psychometric evaluation of the BCTOS-12, the acceptability was supported by a high response rate (85%) and a low frequency of missing responses (<3%) on the questionnaire, except for “scar tissue” with a missing data rate of 7.8%. To complete the validation process, we also examined the reliability and the validity of the BCTOS-12 questionnaire. Concerning the reliability, the internal consistency was examined. The internal consistency evaluates whether all items of the designated scale measure the same concept and are related to each other, though each item should contribute some unique information as well. High values for McDonald’s Omega indicated a good internal consistency of the BCTOS-12 with robust and consistent subscales, i.e., the Aesthetic Status and the Functional Status.

Furthermore, good validity is the most important indicator of the quality of a questionnaire. More specifically, better validity may result in a better power of the PROM to differentiate between “good” and “poor” outcomes [33]. In comparison to the BCTOS-22 with its 22 items, the BCTOS-12 shows an improved convergent validity [21]. This was demonstrated by an improved correlation structure between the subscales of the BCTOS-12 and the validated subscales of the EORTC QLQ C30 BR23. Compared to the results we previously reported on the BCTOS-22 [21], the Aesthetic Status of the BCTOS-12 showed higher correlations to the “body image” score of the EORTC QLQ C30 BR23 (−0.45 vs. −0.31), and the new Functional Status showed higher correlations to the “physical functioning score” (−0.55 vs −0.43). Additionally, both new subscales showed an improved relationship to the “global health status” (Aesthetic Status: −0.56 vs −0.24; Functional Status −0.48 vs −0.39).

For further interpretation of the score values from the BCTOS-12 questionnaire, a classification in categories could be obtained with the use of quartiles (Q1, median = Q2 and Q3). A categorization into four groups and the differentiation between “good” ($\leq Q1$), “intermediate” ($Q1 < \text{and} \leq Q2$), “fair” ($Q2 < \text{and} \leq Q3$), and “poor” ($> Q3$) outcome could be feasible. Therefore, we obtain for the Aesthetic Status “good” (1.00–1.63), “intermediate” (1.64–2), “fair” (2.01–2.63) and “poor” (2.64–4) and for the Functional Status “good” (1.00), “intermediate” (1.01–1.50), “fair” (1.51–2.25) and “poor” (2.26–4). However, a much larger and multicentric cohort would be needed to ensure the representativeness of the proposed values. A categorization of the results leads to a loss of information, so we strongly recommend the use of the continuous score values (1.00–4.00) for further analyses and interpretation. In Fig. 1 a slight floor effect in the score of the Functional Status can be observed; however, this effect is much smaller than in the initial score of the BCTOS-22 Functional Status [21].

PROM are increasingly used in clinical studies, routine management, and the decision making process. Besides the BCTOS, the Breast-Q is a frequently used questionnaire to evaluate patients’ QoL [34, 35]. The Breast-Q is a PROM with various domains including physical well-being, psychosocial well-being, sexual well-being, satisfaction with breast, satisfaction with outcome, and satisfaction with care. Although it is a comprehensive questionnaire with surgery-specific modules, the Breast-Q is quite long, making it difficult to use in its entirety in routine clinical practice [36]. Furthermore, the Breast-Q does not include a specific domain for the aesthetic or functional outcome. Thus, the BCTOS-12 is a valuable tool with its two specific scales, and it integrates well into the existing landscape of PRO measures after BCS.

The strength of this study was the prospectively collected data, including all eligible patients undergoing BCT at the University Hospital of Heidelberg. Further, the study achieved a high participation rate of 85% of patients included before their surgery and returning a questionnaire after surgery. This limits a possible selection bias of the psychometric validation of the BCTOS-12.

One limitation of the study was the homogeneous cohort enrolled at a single center. Furthermore, the psychometric validation of the BCTOS-12 was conducted with a cohort shortly after surgery and we did not evaluate test–retest reliability in this study. Thus, we cannot comment on consistency over time for the BCTOS-12. Also, from the survey of a single time-point, we were unable to assess the responsiveness of the BCTOS-12 to changes over time. However, in a previous study we were able to show the change of the aesthetic outcome over time on the original BCTOS-22 [37].

In conclusion, the BCTOS-12 is a refined, improved, and now validated instrument. It can be used in clinical studies and routine management for the evaluation of the aesthetic and functional outcome after BCS. Consisting of only 12 items on two distinct subscales, the BCTOS-12 is easy to use for both patients and physicians.

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Data availability The anonymized data set used and analyzed during the current study is available from the corresponding author on reasonable request.

Compliance with ethical standards

Conflict of interest All authors declare that they have neither a financial nor a non-financial conflict of interest with regard to this paper.

Ethical approval The study was approved by the Ethics Commission of the Medical School of the University of Heidelberg. All patients gave their written informed consent to participate.

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