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## Original article

## Development and psychometric validation of a shorter version of the Breast Cancer Treatment Outcome Scale (BCTOS-12)



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#### ABSTRACT

Objectives: Aesthetic and functional outcomes after oncoplastic breast-conserving surgery (BCS) are directly related to the patients' quality of life (QoL). The Breast Cancer Treatment Outcome Scale (BCTOS) is a validated but burdensome questionnaire for the assessment of these outcomes. The aim of the study was to strengthen and focus the BCTOS instrument by reducing the number of items and subscales without loss of information and validity.

Methods: This study used a dataset of 871 patients with stage 0 - III breast cancer, from a prospective cohort study, who underwent BCS. We investigated correlations and other criteria of homogeneity of the BCTOS items to identify redundancies. An exploratory factor analysis was used to remodel the itemfactor structure. Correlation and linear regression analysis with validated QoL subscales assessed the convergent and discriminant validity of the modified BCTOS structure.

Results: The factor analysis revealed two distinct subscales for aesthetic and functional outcomes. It was possible to reduce the 22 items of the original BCTOS to 12 items, thus the "BCTOS-12". The two new scales had very good internal consistency: Cronbach's  $\alpha = 0.86$  for the new Aesthetic Status subscale and  $\alpha=0.81$  for the new Functional Status subscale. Bootstrapping confirmed the item-factor structure for all 10,000 samples, remarkably.

Conclusion: The modified BCTOS questionnaire with only 12 items (BCTOS-12) is shorter, easier to interpret, and shows good validity.

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## 1. Introduction

One of the main reasons that breast cancer patients opt for

breast-conserving surgery (BCS) instead of mastectomy is the better aesthetic and functional outcomes, leading to better quality of life (QoL). In BCS, various oncoplastic techniques aim to further

Abbreviations: BCS, breast-conserving surgery; BCTOS, Breast Cancer Treatment Outcome Scale; ECOG, Eastern Cooperative of Oncology Group; EORTC, European Organization for Research and Treatment of Cancer; QLQ-C30, Quality of Life Questionnaire - Cancer 30 items; QLQ-BR23, Quality of Life Questionnaire - Breast 23 items; QoL, quality of life; SD, standard deviation.

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improve these outcomes [1–8]. In order to comparatively assess these different surgical techniques, there is a need for patient-reported outcome measures that are easy to administer. Patient-reported instruments to evaluate the aesthetic and functional outcomes after BCS range from single questions assessing an overall outcome [9] to questionnaires trying to differentiate between various aspects such as breast size and shape, scars, arm pain, and shoulder movement [10–13].

Among the many available patient-reported outcome measures, the Breast Cancer Treatment Outcome Scale (BCTOS) [11] is a questionnaire that is widely used and validated [14–18]. It addresses the most important aspects of morbidity after BCS with respect to aesthetic and functional outcomes. Its main criterion of outcome measurement is the patient's assessment of the treated breast in comparison to the untreated breast. The original BCTOS comprises 22 items with three subscales: 1) Aesthetic Status, 2) Functional Status, and 3) Breast Sensitivity Status.

Years of using the BCTOS have led us to believe that it ought to be shortened. The third subscale — Breast Sensitivity Status — may be viewed as a further aspect of the Functional Status and therefore provides only a minor gain of additional information. 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.

Any shortened version of the BCTOS should be easier to administer yet with no noticeable loss of information, and it should have psychometric properties comparable to or better than the original full version. The aim of this study was to create such a shorter version of the BCTOS.

#### 2. Material and methods

## 2.1. Ethics

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.

#### 2.2. The original Breast Cancer Treatment Outcome Scale (BCTOS)

The BCTOS was designed to assess women's subjective evaluation of the aesthetic and functional outcomes after breast conservation surgery [11]. The original questionnaire contains 22 items (henceforth referred to as BCTOS-22), which are assigned to three internally consistent subscales: 1) Functional Status, 2) Aesthetic Status, and 3) Breast Sensitivity Status; (for details, see Appendix A). Patients are instructed to rate each item of the BCTOS on a four-point scale evaluating the differences between the treated and the untreated breast (1 = no difference, 4 = large difference). The score for each subscale is the mean of the ratings over all items belonging to that subscale. A higher score reflects a poorer status (i.e. a larger difference between the treated and the untreated breast).

## 2.3. The European organization for research and treatment of cancer (EORTC) C30-BR23 questionnaire

We chose the EORTC Cancer Quality of Life Questionnaires (QLQ) C30 and BR23 out of all standard QoL instruments for breast cancer patients, because they are validated in several languages [19], as required by the EORTC [20], including German [21]. This questionnaire consists of a general module, the QLQ-C30 (whereby

"C30" presumably means "cancer" and 30 items), and a breast cancer specific module, the QLQ-BR23 (whereby "BR23" presumably means "breast" and 23 items). The resulting scores 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 level of overall health, but a high score for a symptom scale represents a high level of symptoms. A validated global summary score for the QLQ-C30 was also used [22].

#### 2.4. Study population

Our psychometric evaluation of the BCTOS questionnaire makes use of a prospectively acquired dataset of patients who underwent breast conserving therapy, between 29 August 2007 and 14 September 2012 [14]. The analysis includes patients meeting the following inclusion criteria:

- primary, unilateral, histologically proven breast cancer, treated conservatively;
- Eastern Cooperative of Oncology Group (ECOG) performance status <2;</li>
- ability to read German.

In that prospective cohort study, breast cancer stages  $0-\mathrm{III}$  were included before their first breast-conserving surgery. Most of the patients were diagnosed with invasive ductal carcinoma with a tumor size less than 2 cm. The patients were operated unilaterally with breast-conserving surgery, using oncoplastic techniques as described by Hoffmann and Wallwiener [23]. Patients completed the BCTOS and the EORTC QLQ C30 and BR23 shortly after the operation (median 4 days after surgery).

### 2.5. Statistical methods

Descriptive statistics was used to characterize the study sample. In the case of missing data, we used the mean of the remaining items as the score for that subscale. Further statistics (e.g. factor loadings, correlations) were calculated based on pairwise complete data.

The statistical analysis of the questionnaire was structured into three main parts. First, in order to assess the robustness of the number of subscales, we considered various criteria to assess the number of relevant factors within an exploratory factor analysis. Details on the applied factor algorithm are provided below. We applied the Kaiser criterion (Eigenvalues >1), a scree plot analysis, and a parallel analysis, being aware that the resulting factor structures might differ.

Second, we identified items that were highly correlated, showing high agreement rates (high inter-item correlations) or low loadings or cross-loadings on factors. Correlations between two individual items were assessed using Spearman's rank correlation coefficient and Cohen's kappa coefficients. If two or more items showed a high agreement, those items were combined into a single new item. To mimic the answers of new combined items within the existing data set, we calculated the corresponding integer-rounded mean of the original item values; the new scores of the subscales were calculated as the mean of the items belonging to that subscale, as for the BCTOS-22. Additionally, we considered other key statistical parameters of an item analysis (e.g. item-total correlation, homogeneity, item difficulty) and compared them to the previous

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