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A body image scale for use with cancer patients

P. Hopwood [a,*], I. Fletcher [a], A. Lee [a], S. Al Ghazal [b]

[a] *CRC Psychological Medicine Group, Stanley House, Christie Hospital NHS Trust, Wilmslow Road, Withington, Manchester M20 4BX, UK*
[b] *Professioral Unit of Surgery, Nottingham City Hospital, Hucknall Road, Nottingham NG5 1PB, UK*

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Abstract

Body image is an important endpoint in quality of life evaluation since cancer treatment may result in major changes to patients' appearance from disfiguring surgery, late effects of radiotherapy or adverse effects of systemic treatment. A need was identified to develop a short body image scale (BIS) for use in clinical trials. A 10-item scale was constructed in collaboration with the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group and tested in a heterogeneous sample of 276 British cancer patients. Following revisions, the scale underwent psychometric testing in 682 patients with breast cancer, using datasets from seven UK treatment trials/clinical studies. The scale showed high reliability (Cronbach's alpha 0.93) and good clinical validity based on response prevalence, discriminant validity ($P < 0.0001$, Mann–Whitney test), sensitivity to change ($P < 0.001$, Wilcoxon signed ranks test) and consistency of scores from different breast cancer treatment centres. Factor analysis resulted in a single factor solution in three out of four analyses, accounting for $> 50\%$ variance. These results support the clinical validity of the BIS as a brief questionnaire for assessing body image changes in patients with cancer, suitable for use in clinical trials.

Keywords: Assessment; Body image; Cancer; Clinical trials; Questionnaire

1. Introduction

Cancer treatment may result in major alterations of body image through loss of a body part, disfigurement, scars or skin changes. Radiotherapy may cause tissue damage with insidious changes over many years, the effects of surgery are more immediate but often permanent, whereas transient, reversible changes (e.g. hair loss) may result from systemic chemotherapy. More general changes, such as weight gain may be intermediate in reversibility and duration. Thus, large numbers of patients across many disease groups and treatment types can be affected.

An extensive body of literature on the cosmetic results of surgery now exists: this has mainly focused on breast cancer [1–3] and other common cancers are less well represented [4–6]. Body image has been a key determinant of differences in quality of life (QL) when comparing mastectomy and breast conserving treatments in a variety of settings [7–16], but a wide range of severity and frequency of body image outcomes has been reported, due largely to differences in the methods of measurement. Moreover, the psychometric properties of measures used in earlier studies were often inadequately described or tested.

Body image is, therefore, an important component of the QL assessment, but a review of the literature [17] revealed the lack of a suitable scale to measure body image in cancer patients, particularly in the clinical trials setting. This was an important omission given the increasing focus on QL endpoints and the need to measure the subjective impact of treatment on surviving patients.

The use of observer measures of cosmesis has not proved satisfactory, as results of patient — observer ratings often show poor concordance [18–20]. As with other QL measures, this suggests that the patients' own views are important for treatment evaluation. Thus, a brief, psychometrically robust scale was needed, applicable across disease sites or treatment modalities, which could be used in conjunction with other multidimensional QL measures, particularly in the clinical trials setting.

* Corresponding author. Tel.: +44-161-446-3683; fax: +44-161-446-8103.
E-mail address: penelope.hopwood@man.ac.uk (P. Hopwood).

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An initiative was taken to develop a brief patient self-report measure in collaboration with members of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group. It was envisaged that the scale would be used as a module in conjunction with the EORTC QLQ-C30 [21] in clinical trials or studies where body image was an important outcome.

The methodology did not rely on a particular theoretical model, as there was (and indeed still is) no consensus on the definition of body image disturbance. Models have been proposed (particularly with reference to eating disorders), but differ considerably in the criteria and or constructs required to measure body image [22,23] and no unitary theory has yet emerged to embrace all of these approaches. The authors took a patient-focused approach, which had formed the basis in the development of cancer-specific QL scales [21,24]. The results of two stages of development of the body image scale (BIS) are now reported. The scale was designed to be applicable to patients with any cancer site and any form of cancer therapy.

Four items from the full BIS have been incorporated into the EORTC Breast Cancer Module [25] and one (''difficult to look at self naked'') has been used in a BIS for survivors of childhood cancer [26]. The BIS is currently in use in several UK multicentre randomised trials of treatment for breast cancer, as well as many smaller psychosocial studies in the UK and Europe.

2. Patients and methods

2.1. Development and preliminary field testing of Body Image Scale (BIS): Version 1

The initial stages of development were undertaken before the publication of Guidelines for module development [27], but followed broadly similar lines.

2.1.1. Item generation and scale construction

Items were derived from the literature, discussion with health professionals and extensive interviews with breast cancer patients. This included items from recently completed trials in breast cancer [6,24]. A 10-item scale was produced for testing. In the interest of brevity, and to avoid overlap with disease-specific modules, items were excluded if they were site-specific (e.g. use of a breast prosthesis) or duplicated (e.g. feeling body damaged as a result of treatment). The 10 test items comprised affective items (e.g. feeling feminine, feeling attractive), behavioural items, (e.g. find it hard to look at self naked, avoid people because of appearance), and cognitive items (e.g. satisfied with appearance, or with scar).

Five were presented positively (e.g. ''Have you been feeling feminine/masculine?'') and five negatively (e.g. ''Did you find it difficult to look at yourself naked?''). Respondents were asked to consider any changes since diagnosis or treatment by selecting the appropriate response category for each question. The four options for rating body image changes were selected to be consistent with current QL measures, namely ''not at all'' (score 0), ''a little'' (score 1), ''quite a bit'' (score 2) and ''very much'' (score 3). The 10 item scores were then summed to produce overall summary score for each patient, ranging from 0 to 30. Zero scores represented no symptom/distress and higher scores represented increasing symptoms/distress. Other forms of logarithmic conversion could also be applied.

Instructions on the scale asked patients to complete the questionnaire with reference to the past week, to be in keeping with the timeframe of QL measures [23]. This timeframe was considered optimal, as it would be sensitive to changes with treatment, but not too long leading to a tendency to complain.

The scope of the scale was designed so that it could be used with any cancer patient group likely to experience body image concerns.

2.1.2. Preliminary field testing

The scale was administered to a heterogeneous cohort of 276 cancer patients participating in a prospective study of psychosocial adjustment, carried out by the Cancer Research Campaign (CRC) Psychological Medicine Group in Manchester. Patients were newly diagnosed with primary breast, colorectal, testicular, cervical cancer and lymphoma and were treated by surgery, radiotherapy, chemotherapy or a combination of these. Thus, a wide range of treatment effects were involved including loss of breast or testis, provision of a colostomy, loss of hair, weight loss or gain, or loss of internal organs. The questionnaire was administered at the same time as a 1 or 2 year follow-up interview at the patient's home. Trained research interviewers systematically debriefed patients after completion of the scale to determine the following: (i) ease of understanding and acceptability of items; (ii) redundancy of items; (iii) missing items; (iv) overall ease of completion.

Patients were encouraged to make additional comments where appropriate. Responses were annotated for each person completing the scale.

Patients were mailed the questionnaire for completion on a second occasion one month later.

2.1.3. Analysis of psychometric properties

The following analyses using the Statistical Package for the Social Sciences (SPSS) were carried out on the full sample and on the breast cancer subgroup to assess the psychometric properties of the scale.

2.1.3.1. Reliability. Internal consistency was measured using Cronbach's alpha reliability coefficient, with a minimum value of 0.70 for retaining items.

Test–retest reliability was measured using the Pearson correlation coefficient and Wilcoxon signed ranks test

2.1.3.2. Clinical validity. Endorsement of test items and indications of redundancy or omission of important items was examined.

Response prevalence (the frequency with which positive scores (1–3) for each questionnaire item were obtained: a criterion value of response by $\geqslant 30\%$ of the sample was used.

Discriminant validity was assessed on the basis of known group comparisons, such as expected differences in women treated by mastectomy or conservative surgery.

Consistency of scores between like patient samples.

3. Results

The interviewed sample comprised 276 patients (75% ($n=207$) female, 25% ($n=69$) male) with cancer of the breast ($n=160$, 58%), large bowel ($n=37$, 13%), testis ($n=38$, 14%), gynaecological cancer ($n=38$, 14%) or lymphoma ($n=3$, 1%). Thus, not all patients had treatment with visible body alterations. 153 patients (55%) were assessed 1 year after diagnosis and 123 (45%) 2 years after diagnosis. The subgroup samples were broadly comparable at these two timepoints. 134 (49%) patients returned postal questionnaires one month after the first assessment: of these 46% ($n=62$) were from the 1-year follow-up group and 54% ($n=72$) were from the 2-year follow-up group.

3.1. Reliability

3.1.1. Cronbach's alpha coefficients

Cronbach's alpha coefficients for the 10-item scale in the full sample, and breast cancer subgroup, completed at interview and by post, were all within the required range with values of 0.78, 0.85, 0.78 and 0.85, respectively. These values were above the recommended criterion value of 0.70.

3.1.2. Test–retest reliability

Scores were compared for those patients with matched data on two occasions one month apart ($n=94$). Sixty-four per cent of item scores were identical on the two occasions and 89.3% item scores differed by a score of one, with complete agreement ranging from 48.5% (Q2 and Q9) to 89.2% (Q7). A significant relationship was shown between the two sets of summary scores (rho = 0.70; $P=0.001$ Pearson correlation coefficient) and there was no significant change in scores between the two occasions ($P=0.51$ Wilcoxon matched-pairs signed ranks test).

3.2. Clinical validity

3.2.1. Endorsement of test items

At the debriefing interviews, all items were considered understandable and acceptable: there were no indications to add or delete items on this basis.

A quite frequent comment was made that positively phrased items (e.g. "I feel sexually attractive") were awkward or embarrassing to answer as patients did not normally describe themselves in this way.

3.2.2. Response prevalence

Full sample: between 38.5% and 94% patients self-rated with scores >0 (i.e. indicating a change in some aspect of body image) on 7 out of the 10 question items and hence reached the 30% response rate criterion. The items failing to reach criterion were: feeling self-conscious, ability to look at self naked and avoidance of other people, with response rates of 28.5%, 25.2% and 8.9%, respectively. This finding was consistent with the fact that there were no visible signs of altered body image in certain subgroups of patients.

3.2.3. Breast sample

Only one item failed to reach criterion (avoiding people because of feelings about appearance) with a 6.3% response.

3.2.4. Discriminant validity

BIS summary scores for women treated by mastectomy were compared with those for women treated by conservative surgery. This subgroup contained women assessed at one and two years post surgery. Surprisingly, the scale did not show an expected difference in scores between these groups (data not shown). The length of time from surgery may have had an impact on the women's adjustment and minimised differences in body image, or the scale was performing inadequately in terms of its discriminant ability.

3.2.5. Consistency of results between samples

The mean summary score for the full sample was 8.62 (standard deviation (S.D.) 5.02) range 0–27, with a median score of 8.00. The values for the sample split by time of assessment and by disease subgroup are shown in Table 1. All subgroups had comparable scores except for the 3 lymphoma patients, who may not be representative. Mean scores of the year 2 sample were consistently higher than those for the year 1 patients, but are not strictly comparable statistically as they are different patient groups. The greater difference in scores within the gynaecological cancer subgroup may be due to small numbers rather than a true difference.

Table 1
BIS version 1: descriptive statistics for first field study sample

Sample	BIS at year 1			BIS at year 2		
	Mean	S.D.	Range	Mean	S.D.	Range
Full sample	7.78	5.16	0–24	9.46	5.39	0–27
Breast	8.07	5.02	0–24	9.00	4.70	0–22
Large bowel	7.89	3.14	4–15	9.95	4.71	0–16
Testis	6.06	4.10	0–13	7.24	4.44	0–15
Gynaecological	7.67	5.15	0–16	11.70	7.35	0–27
Lymphoma	13.67	4.16	9–17	(No year 2 patients)		

BIS, body image scale; S.D., standard deviation.

3.3. Summary of results of initial field testing

Overall, the performance of the scale was satisfactory, but there was concern that patients were uncomfortable responding to positively phrased items. It was decided to redraft the scale using all negatively phrased questions. Advice was taken from members of the EORTC QL Study Group on how these should be presented, given the potential problems in the English language of using a double-negative in the question (e.g. "Have you felt less physically attractive....?" and response "not at all").

It was decided to retain the item with a low response prevalence because of its potential importance in identifying more severe body image disturbance.

3.4. Psychometric properties of Body Image Scale: Version 2

3.5. Sources of data

Version 2 data were obtained from a series of clinical studies in breast cancer (S. Al-Ghazal, Nottingham City Hospital, Nottingham, UK; A. Davies, Asta Medica Ltd, Cambridge, UK) (shown in Appendix A) [29–33] to further examine the structure and performance of the scale. The sample consisted of 682 patients: the two largest patient samples contributing to the analysis were 254 women treated by wide local excision (WLE, sample A) and, 202 treated by mastectomy (Mx, sample B). These patients were assessed on a single occasion ranging from 2 weeks to 232 months from the time of primary surgery. Five smaller research samples (C–G) were included to examine the consistency of results, to test for sensitivity to change and to pilot application of the scale in other settings. For example, sample G comprised 57 women who had undergone bilateral prophylactic mastectomy because of a high genetic risk of breast cancer.

3.6. Statistical analysis

The questionnaire was scored as described earlier. If there were missing scores for one or two items an imputed item score was calculated from the mean of the items to which the patient had responded. This was done for 28 forms in which 25 had one missing item and 3 had two missing items. The most frequent missing items were for question 6 (feeling less sexually attractive): 14 (2%) forms, and question 10 (dissatisfied with scar): 8 (1%) forms. The remaining 6 forms had missing items affecting 7 other questions.

Analyses were carried out using the subgroups, as well as the full data set from 682 patients, to test for the consistency of results. The properties to be tested were: (1) reliability: Cronbach's alpha statistic; (2) clinical validity: response prevalence, discriminant validity, sensitivity to change, consistency of results; (3) scale structure: factor analysis.

3.6.1. Reliability

Reliability of the 10-item scale was calculated separately for the two largest subgroups (A and B) and for a pooled dataset of 226 patients from subgroups C–G. Cronbach's alpha statistics for the BIS in these subgroups were 0.91, 0.91 and 0.86, respectively. No item had a value less than 0.84 in these comparisons. Cronbach's alpha statistic for data from the full sample ($n = 682$) was 0.93: item alphas ranged between 0.92 and 0.93.

3.6.2. Clinical validity

3.6.2.1. Response prevalence. Response prevalence (the frequency of scores >0 in any item) was a component analysis recommended in the EORTC guidelines for scale development. It was assessed for each scale item for the full dataset and for subgroups A and B, representing conservatively treated patients and patients undergoing mastectomy (Table 2). In the overall sample and mastectomy subgroup (B), all items fulfilled the EORTC response criteria (i.e. were answered with a score of >0 by $\geqslant 30\%$ respondents). The response rate was lower in the WLE subgroup (A), consistent with the improved body image in this group: six items were rated with item scores >0 by over 30% women and three by over 20% of the women. The item least frequently used in this subgroup (question 7) was rated by two-thirds of women treated by mastectomy and, therefore, deemed important.

3.6.2.2. Discriminant validity. Published data would lead us to expect a difference in mean body image scores for women treated by mastectomy compared with those receiving conservative surgery. BIS scores were compared between samples A (WLE) and B (Mx): the difference in median scores was highly statistically significant (sample A, median:3.00; sample B, median:13.00, $P < 0.001$, Mann–Whitney test). Descriptive statistics are presented in Table 3.

The analysis was repeated using data from all patients treated by WLE or by mastectomy, irrespective of stage of disease (but excluding reconstructed patients) and again showed a significant difference between scores (all

Table 2
BIS: response frequency for individual items

Scale item	Full sample % response $n=682$	Sample A (WLE) % response $n=254$	Sample B (Mx) % response $n=202$
1 Self-conscious	51.0	40.2	65.9
2 Less physically attractive	57.0	39.8	78.5
3 Dissatisfied with appearance	42.1	23.2	64.1
4 Less feminine	47.1	24.4	73.3
5 Difficult to see self naked	49.9	30.7	75.2
6 Less sexually attractive	64.2	55.9	80.7
7 Avoid people	33.6	11.0	66.7
8 Body less whole	49.4	31.5	73.7
9 Dissatisfied with body	48.1	32.2	70.7
10 Dissatisfied with scar	47.5	28.0	66.8

BIS, body image scale; WLE, wide local excision; Mx, mastectomy.

WLE, median: 2.50; all mastectomy, median: 12.00, $P<0.0001$, Mann–Whitney test).

3.6.2.3. Sensitivity to change. Responsiveness is an important property of scales evaluating change over time after cancer therapy. Body image data were used from sample C, a psychosocial study of 56 women assessed 2 weeks and 4 months postoperatively. 29 (52%) were treated with conservative surgery (WLE) and 27 (48%) by mastectomy. One mastectomy patient had missing data at follow-up and was not evaluable. There was a significant increase in the reporting of body image disturbance over time, both for the overall sample (Wilcoxon $z=-5.08$: $P<0.001$) and for the two subgroups, (WLE, $P=0.031$; mastectomy, $P<0.0001$, Wilcoxon signed ranks test) as shown in Table 4. The surgical subgroup scores also differed significantly from each other at each timepoint: 2 weeks postoperatively, $P=0.051$; 4 months postoperatively, $P=0.004$, Mann–Whitney test.

3.6.2.4. Consistency of results from different data sources

Descriptive statistics. As shown in Table 3, data from all patient sources showed consistency in BIS scores across type of surgery. Lowest scores were found for patients treated by WLE, highest for patients treated by mastectomy and intermediate, in most cases, for patients who had undergone breast reconstruction. The unusually low scores for the mastectomy patients in sample F were attributed to selection bias and small

Table 3
BIS: descriptive statistics for all samples

Sample	Sample size	Type of surgery	BIS scores				
			Mean	S.D.	Median	Minimum	Maximum
ALL	682	All	7.64	7.22	6.00	0	30
A	254	WLE	4.27	5.14	3.00	0	29
B	202	Mx	14.22	5.98	13.00	2	30
C	Total $n=55$[a]						
	$n=29$	WLE	4.24	5.30	3.00	0	21
	$n=25$	Mx	8.68	6.22	9.00	0	23
D	Total $n=47$						
	$n=32$	Mx	7.09	5.24	8.00	0	19
	$n=8$	WLE	10.57	10.58	6.00	0	30
	$n=7$	No surgery	3.00	4.44	0.50	0	10
E	Total $n=35$						
	$n=14$	WLE	4.71	5.06	2.00	0	17
	$n=17$	Mx + rec	6.88	6.64	5.00	0	24
	$n=4$	Mx	8.00	5.72	9.50	0	13
F	Total $n=32$						
	$n=10$	Mx + rec	4.20	6.93	1.50	0	21
	$n=11$	Mx alone	4.18	3.89	4.00	0	14
	$n=11$	Awaiting rec	17.27	6.45	17.00	4	30
G	Total $n=57$						
	$n=50$	Mx + rec	5.14	5.29	4.00	0	26
	$n=7$	Mx alone	6.57	10.98	0.00	0	25

BIS, body image scale; S.D., standard deviation; WLE, wide local excision; Mx, mastectomy; rec, reconstruction.
[a] One additional patient had Mx + reconstruction (BIS score 12).

Table 4
Longitudinal data to show sensitivity to change in BIS score

Type of surgery	BIS score (mean/S.D./median/range)	
	2 weeks postop.	4 months postop.
Full sample	2.40 (3.50) 1.00 0–14	6.40 (6.10) 4.00 0–23
WLE	1.59 (2.71) 1.00 0–12	4.24 (5.30) 3.00 0–21
Mx	3.31 (4.09) 2.00[a] 0–14	8.81 (6.13) 9.00[b] 0–23

BIS, body image scale; S.D., standard deviation; WLE, wide local excision; Mx, mastectomy; postop., postoperatively.
[a] Comparison between the two subgroups at 2 weeks postoperatively $P=0.051$.
[b] Comparison between the two subgroups 4 months postoperatively $P=0.004$.

samples. The standard deviations appear rather large in some of the samples due to the effect of a small number of very high scores (data not shown).

Comparison of BIS scores by age. An effect of age on body image has been reported in the literature with younger women having more body image concerns [34], although other investigators have failed to find such an association. Data for the full sample was, therefore, split at age 55 years to explore differences in BIS scores that corresponded approximately to women pre and post-menopause. The analysis was repeated in the two largest surgical subgroups (A and B) to examine for any confounding effect of type of surgery on age. Results showed significantly higher scores in younger patients and the finding was consistent in the surgical subgroups (Table 5).

Comparison of BIS scores by time since primary surgery. A significant relationship between problems with cosmetic outcome and time elapsed since treatment has been reported [20].

Although most of the patient samples used were from cross-sectional studies, a simple analysis of the effect of time on BIS scores was undertaken by splitting the data into two groups according to time from primary surgery

Table 5
Comparison of BIS scores by age[a]

Sample	Age (years)	Sample size (n)	BIS scores				
			Mean	Median	S.D.	Min	Max
Full	<56	366	8.34	6.00	7.47	0	30
	$\geqslant 56$	300	6.96	5.00	6.89	0	30 ($P=0.011$)[b]
Mx	<56	99	15.16	14.00	6.11	0	30
	$\geqslant 56$	103	13.31	12.00	5.74	0	28 ($P=0.023$)[b]
WLE	<56	152	5.34	4.00	5.86	0	29
	$\geqslant 56$	102	2.68	1.50	3.25	0	14 ($P=0.0001$)[b]

BIS, body image scale; Mx, mastectomy; WLE, wide local excision.
[a] Age information was missing for 16 patients.
[b] Comparison of BIS scores by age-group: Mann–Whitney U test.

Table 6
Comparison of BIS scores by time since primary surgery[a]

Time since surgery	BIS mean	(S.D.)	Median	Minimum	Maximum
$\leqslant 6$ months ($n=106$)	3.43	(4.27)	1.00	0	16
>6 months ($n=563$)	8.52	(7.39)	7.00	0	16 $P=<0.0001$[b]

BIS, body image scale; S.D., standard deviation.
[a] Information was missing for 13 patients.
[b] Comparison of BIS scores by time since primary surgery: Mann–Whitney U test.

($\leqslant 6$ months versus >6 months). The full dataset was split by time since primary surgery ($\leqslant 6$ months versus >6 months). This cut-off point was selected as the literature has suggested a worsening of body image concerns in the first few months following surgery [34,35]. Results shown in Table 6 indicated significantly higher BIS scores in assessments made more than 6 months from the time of first surgery.

3.6.3. Scale structure

Factor analysis is a statistical technique that examines the relationships between component items on a scale and groups together similar items. It is used to confirm the structure and validity of a scale. Scale structure was first examined using General Least Squares Factor Analysis on the full sample (FS) and on the component subgroups, namely the largest WLE and mastectomy subgroups (A and B) and on all remaining subjects (groups C–G (Appendix A), $n=226$). These analyses showed a generally consistent structure between samples with a single factor solution in three out of the four analyses explaining 57.55, 50.18 and 53.05% of the variance, respectively as shown in Table 7. Factor analysis on the mastectomy subgroup B resulted in a two-factor solution, in which the scale items 1–7 (appearance/

Table 7
Factor analysis

Sample: Item no.	Total (FS) factor	WLE (A) factor	Mx (B) factor		Mixed data (C–G) factor	All Mx factor
	1	1	1	2	1	1
1	0.700	0.621	0.685		0.829	0.686
2	0.830	0.734	0.737		0.832	0.786
3	0.692	0.625			0.768	0.607
4	0.835	0.559	0.637		0.876	0.781
5	0.758	0.622	0.503		0.716	0.681
6	0.821	0.574	0.696		0.544	0.812
7	0.683	0.353			0.706	0.577
8	0.769	0.674		0.684	0.740	0.678
9	0.761	0.672		0.708	0.789	0.659
10	0.717	0.538		0.542	0.301	0.659
% variance	57.55	50.18	26.93	18.76	53.05	48.51

WLE, wide local excision; Mx, mastectomy; FS, full sample.

attractiveness factor) explained 26.93% of the variance and items 8–10 (body satisfaction factor) explained 18.76% of the variance. Two items (dissatisfied with appearance when dressed and avoiding people because of feelings about appearance; items 3 and 7) were not included in this two-factor solution.

A 10-item scale has been developed to show changes in body image in cancer patients which performed well on testing of its reliability, clinical validity and scale structure. Psychometric properties were consistent between different cancer groups and between heterogeneous breast cancer samples. Factor analysis confirmed that the scale is a unitary measure in all but one analysis. The two-factor solution in the smaller mastectomy dataset gave an understandable result (items 8–10 are more likely to affect mastectomy patients), but one that was not reproducible. Exploratory analyses showed an age effect and increased body image disturbance over time following surgery.

4. Discussion

We have described the construction of a brief body image scale that can be used in conjunction with other QL measures in clinical trials or as a specific scale in psychosocial research. Development took place following broadly similar lines to those now recommended by the EORTC Study Group on QL. The generation of items was more limited than the current guidelines would now require, but was aided by published research. The measure is of potential value in psycho-oncology since it is both brief but psychometrically robust.

Initial development was carried out in a broad range of cancer patients and the coverage proved acceptable to both male and female patients with a range of body image concerns. However, the formatting of responses required changes so that patients were not inhibited in reporting changes in body image. Positively phrased items were problematic in this regard. The questionnaire asks for self-ratings that reflect change after diagnosis or treatment, to enable acceptability to a wide range of patients. One item (''have you been dissatisfied with the appearance of your scar?) would not always be applicable and this can be indicated by checking an additional box on the form so that scoring and analysis can take account of this. Extensive psychometric testing was then restricted to patients with breast cancer, but confirmed the psychometric performance in all important aspects. Further datasets are now required to confirm the performance in other patient groups and provide reference data for comparison with other studies. This would be particularly useful for re-examining the factor structure in patient samples with other types of cancer.

In order to be used in international trials or cross-cultural studies, the scale now requires further development in translation. Four BIS items, selected on the basis of relevance and face validity (i.e. they appeared to measure what they were designed to measure), have already been incorporated in the EORTC Breast Cancer Module (QLQ-BR23) [25]. It seems likely that the performance of the full scale could be replicated and it has already been successfully translated into several European languages.

It should be noted that the scoring of body image items within the EORTC modules [25] follows the convention of the EORTC QLQ-C30, with high scores on functional items representing healthy levels of functioning and high scores on symptom items representing high symptom burden. In the analyses reported in this paper, all items have been scored as symptom items for consistency. This should be noted when comparing results. The scale can be scored according to the needs of the study and linear transformation (to a score range of 0–100) of the raw scores computed as appropriate.

A clinical threshold score for body image disturbance is not yet available. The BIS was developed for use in trials where the main need was to make comparisons between patient groups. However, it is important that differences in scores in clinical studies are interpretable and further research is needed to define appropriate cut-off scores. The scale could then be a valuable tool for clinical practice, so that patients could be better targeted for intervention. The setting of a threshold is problematic, however, as there are no agreed diagnostic criteria for body image disturbance or standardised interview assessments.

Many other measures of body image exist [36–40] developed for other patient groups, such as those with eating disorders or Body Dysmorphic Disorder. These may lend themselves to modification for use with cancer patients, but at present their sensitivity and specificity in the cancer setting is unknown.

The scale was developed along pragmatic guidelines that have proved successful worldwide in the construction of core quality of life measures. It is acknowledged, however, that a theoretical underpinning would also be desirable. Given current differences in body image constructs, this could result in several kinds of measures being developed, for example, using a cognitive–behavioural paradigm, self-discrepancy theory, or a subjective–objective perception of body image disturbance. All of these approaches are of interest and have their strengths and weaknesses. The BIS leans more towards an affective–cognitive–behavioural model of body image disturbance, which evolved from the items generated with the most frequency by patients and health professionals.

We consider a 10-item scale to be a minimum number of items for measurement given the results of our most recent testing in breast cancer patients, but wish to retain a structure that is sufficiently general to be

applicable across disease sites and treatment situations. Additional items could be developed for specific applications, but the psychometric properties of the scale would then need reconfirming.

The exploratory analysis concerning the effect of age supports other research [34], but should be repeated in other cancer groups. Time since surgery has been reported to be an important independent variable in quality of life studies in breast cancer [41], but data specifically relating to body image is lacking. It is important that both early (e.g. surgical) and late (e.g. radiotherapy) effects are evaluated. The time effect on body image is important to clarify since it would have to be controlled for in considering other factors that could impact on outcome. There are also implications for the planning of appropriate assessment points in clinical trials, as well as in intervention studies.

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Appendix A. Sources of Data

Group [Ref.]	*n*	Source	Mean age (S.D.)	Details of study
A [28]	254	Professorial Unit of Surgery, Nottingham City Hospital	52.4 (8.7)	Cross-sectional survey of breast cancer patients following wide local excision
B	202	Professorial Unit of Surgery, Nottingham City Hospital	54.9 (9.1)	Cross-sectional survey of breast cancer patients following mastectomy
C [29]	55	Department of Surgery, University Hospital of South Manager	58.4 (10.7)	Longitudinal psychosocial study of post-operative breast cancer patients
D	47	16 UK centres	68.8 (13.0)	Multicentre RCT of skin metastases in advanced breast cancer
E	35	Frenchay Hospital, Bristol University, West of England	52.9 (12.0)	Longitudinal psychosocial of study of post-operative breast cancer patients
F [32]	32	Department of Surgery, University Hospital of South Manchester	54.1 (12.5)	Cross-sectional psychosocial study of reconstruction in breast cancer patients
G [33]	57	Department of Surgery, Christie Hospital and University Hospital of South Manchester	41.6 (8.2)	Longitudinal follow-up of genetic high risk women following bilateral prophylactic mastectomy

S.D., standard deviation; RCT, randomised control trial.

BODY IMAGE SCALE

In this questionnaire you will be asked how you feel about your appearance, and about any changes that may have resulted from your disease or treatment. Please read each item carefully, and place a firm tick on the line alongside the reply which comes closest to the way you have been feeling about yourself, during the past week.

Name: _____ Date: _____

	Not at all	A little	Quite a bit	Very much
Have you been feeling self-conscious about your appearance?	.....	.....	.....	.....
Have you felt less physically attractive as a result of your disease or treatment?	.....	.....	.....	.....
Have you been dissatisfied with your appearance when dressed?	.....	.....	.....	.....
Have you been feeling less feminine/masculine as a result of your disease or treatment?	.....	.....	.....	.....
Did you find it difficult to look at yourself naked?	.....	.....	.....	.....
Have you been feeling less sexually attractive as a result of your disease or treatment?	.....	.....	.....	.....
Did you avoid people because of the way you felt about your appearance?	.....	.....	.....	.....
Have you been feeling the treatment has left your body less whole?	.....	.....	.....	.....
Have you felt dissatisfied with your body?	.....	.....	.....	.....
Have you been dissatisfied with the appearance of your scar?	.....	.....	.....	.....
	Not Applicable		.....	

Dr P. Hopwood, CRC Psychological Medicine Group, Stanley House, Christie Hospital NHS Trust, Wilmslow Road, Withington, Manchester M20 4BX Tel.: 0161 446 3683 Fax: 0161 446 8103.

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