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ORIGINAL ARTICLE

Development of a Japanese version of the BREAST-Q and the traditional psychometric test of the mastectomy module for the assessment of HRQOL and patient satisfaction following breast surgery

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Abstract

Background An understanding of health-related quality of life (HRQOL) is of utmost importance in both oncological and esthetic breast surgery. The BREAST-Q is a patient-reported outcome (PRO) measure that investigates HRQOL and patient satisfaction before and after breast surgery. The aim of this study was to develop a Japanese version of the BREAST-Q including the mastectomy module, the reconstruction module, the augmentation module and the reduction/mastopexy module, and to assess the psychometric properties of the mastectomy module among Japanese women.

Methods The Japanese version of the BREAST-Q was developed through forward translation, backward translation and patient testing. Traditional psychometric testing of the mastectomy module was administered to 45 post-mastectomy patients.

Results The mastectomy, reconstruction, augmentation and reduction/mastopexy modules were formally developed into Japanese. Despite cultural difference between Japanese women and original target population, the contents were considered to be valid among Japanese woman. With the exception of the sexual well-being subscale, good reliability and validity were evident for the mastectomy module (Test–retest reliability 0.76–0.95, Chronbach's alpha coefficient 0.77–0.98).

Conclusions The BREAST-Q Japanese version is a useful PRO measure for investigating the impact of breast surgery on HRQOL and patient satisfaction. Further validation in younger Japanese women is needed to determine the usefulness of the sexual well-being subscale.

Keywords BREAST-Q · Breast reconstruction · Satisfaction · Health-related quality of life · Breast cancer

Introduction

The concept of health-related quality of life (HRQOL) is essential when discussing the outcome of breast cancer treatment [1, 2]. To date, various patient-reported outcome (PRO) measures [3–9] have been utilized in Japan to collect important information about the impact of breast cancer treatment on the HRQOL [1, 10–14]. However, breast reconstruction is no longer uncommon and studies focusing on esthetic outcomes, HRQOL and patient satisfaction are becoming more important. Thus, new PRO measures that suit the purpose are necessary. For the same reason, PRO measures, such as the Michigan Breast Reconstruction Outcomes Study (MBROS) Satisfaction and Body Image Score [15], the Body Image after Breast Cancer Questionnaire (BIBCQ) [16] and the BREAST-Q [17–19], have been developed overseas.

The BREAST-Q is a PRO measure designed to evaluate the impact of breast surgery on HRQOL and patient satisfaction. It was developed in adherence with international PRO measure guidelines [20, 21]. Since it

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is comprised procedure-specific modules, the BREAST-Q is useful in examining the impacts of each surgery. It covers a variety of breast oncological and esthetic surgeries: mastectomy, breast reconstruction, augmentation, reduction/mastopexy, and breast conserving therapy. One of the advantages of BREAST-Q is the adoption of the Rasch measurement method (RMM). RMM offers the ability to construct linear measurements from original-level data, which is an important aspect of an outcome measure. Moreover, it enables estimates appropriate for individual patient measurement in clinical practice, whereas the classical test theory, which has been the dominant psychometric paradigm in the development of new PRO instruments, generates ordinal measures rather than interval measures, and is useful for group comparison, but is not applicable to individual analyses [19, 22]. Common domains include (1) satisfaction with the breast(s), (2) satisfaction with the outcome, (3) psychosocial well-being, (4) physical well-being, (5) sexual well-being and (6) satisfaction with care. Psychometric tests, both according to the traditional method and using the Rasch analysis revealed its high reliability and validity (Test–retest reliability 0.73–0.96, Cronbach's alpha 0.81–0.96) [17].

Our project to develop the Japanese version of the BREAST-Q was started in 2010 with the permission of both the original author and the MAPI Research Trust (MRT), an organization that manages the copyright of PRO instruments. The four originally released modules of the BREAST-Q, the mastectomy module, the reconstruction module, the augmentation module and the reduction/mastopexy module, had previously been translated into Japanese and were confirmed by MRT in 2013. The Japanese version of the breast conserving therapy (BCT) module, the expectation module and the latissimus dorsi (LD) scale, three modules/scale that were newly added to the original BREAST-Q in 2014, are currently under development. Although the psychometric tests of the translated versions were not required according to the linguistic validation guideline of MRT, we considered this as fundamental elements that could affect the validity and the reliability of the collected data in future studies using the BREAST-Q Japanese version. Therefore, we assessed the psychometric properties of the BREAST-Q Japanese version beginning with the mastectomy module. This paper describes the process of the development of the Japanese version of the above-mentioned four original modules and the traditional psychometric properties of the mastectomy module, including acceptability, test–retest reliability, internal consistency, and construct validity among the Japanese breast cancer population.

Materials and methods

Stage I: development of the Japanese version of the BREAST-Q

The Japanese version of the BREAST-Q was developed formally according to the linguistic validation guidelines of MAPI Research Trust (MRT) [23]. Permission to proceed with this project was obtained from MRT in 2010. We developed Japanese versions of the four primary published modules: reconstruction module, mastectomy module, augmentation module and reduction module (Table 1).

The initial stage included 2 independent forward translations, backward translation and patient testing. The forward translators were both native Japanese speakers and English bilingual. They translated the original BREAST-Q into Japanese independently. These two translations were reconciled into one by the project manager and two forward translators. The reconciled Japanese version was back-translated into English by a translator, a native English speaker and also Japanese bilingual. The project manager and backward translator compared the backward version and the original English version to check if the meanings and concepts were equivalent. After the backward version had been agreed upon by the author of the original BREAST-Q, patient testing was initiated. The purpose of the patient testing was to examine the content validity, acceptability and patient burden. For content validity, we asked the patients if there were any questions unrelated to their diseases or conditions and their surgery. Acceptability referred to whether the questionnaire was easy to read and answer and whether the content was understood as intended. At least five patients per questionnaire were recruited as a panel to test the Japanese version. Participants were recruited by surgeons at outpatient clinics at Okayama University Hospital and at a related clinic for esthetic surgery. Tests were conducted in a private room, in which the patient responded to the questionnaire and a cognitive interview was administered by a researcher. The pilot test resulted in an improved Japanese version of the BREAST-Q.

Stage II: field test of the mastectomy module

BREAST-Q mastectomy module

The mastectomy module aimed to examine the important issues for patients who undergo mastectomy without reconstruction. The subscales of the mastectomy module are: (1) satisfaction with the breast(s), (2) psychosocial well-being, (3) physical well-being, (4) sexual well-being and (5) satisfaction with care (a. satisfaction with the

Table 1 The modules of BREAST-Q

Module/scale	Procedure	Notes	Development of Japanese version
Mastectomy module	Mastectomy		Completed
BCT module	Breast conserving therapy		Ongoing
Reconstruction module	Breast reconstruction	Applicable for both implant breast reconstruction and autologous tissue breast reconstruction.	Completed
		Includes an optional scale to examine satisfaction on donor site of abdominal flap	
LD scale	Breast reconstruction	An optional scale to examine satisfaction and HRQOL on donor site of latissimus dorsi flap	Ongoing
Expectation module	Breast reconstruction	Instrument to examine patients' expectation for breast reconstruction preoperatively	Ongoing
Augmentation module	Breast augmentation		Completed
Reduction module	Breast reduction/mastopexy		Completed (patient testing were not performed)

The mastectomy module, the BCT module, the reconstruction module, the augmentation module and the reduction module have preoperative and postoperative questionnaire. BCT module, LD scale and Expectation module were published in 2014; Japanese versions are under development

surgeon, b. satisfaction with the medical team, c. satisfaction with the office staff). Patient responses to items in each subscale were transformed into summary scores ranging from 0 to 100; higher score indicate better HRQOL and satisfaction. Each of the subscales functions independently and there is no overall or total BREAST-Q score.

Sample and method

Women who underwent mastectomy were recruited to participate in this study at Okayama University Hospital from November 2014 to July 2015. The subjects were included if they had a definite diagnosis of breast cancer, understood Japanese, were 20 years of age and older, and that 6 months had passed since the mastectomy. Patients were excluded if they had undergone breast reconstruction, were currently undergoing radiation therapy or chemotherapy, had a diagnosis of recurrence or metastasis, or were mentally unable to complete the questionnaires. For the assessment of test–retest reliability, we selected medically stable patients as the sample group.

The patients were informed of the study through a nurse during their visit to the oncologists. If they agreed to participate, they were provided with 2 sets of questionnaires with 2 envelopes. They were asked to complete each of the questionnaires over a 2-week interval at home and to return them individually by mail. The questionnaire included a questionnaire about their social background, the BREAST-Q, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast23 (EORTC QLQ-BR23) [4, 5], the Functional Assessment of Cancer Therapy-Breast (FACT-B) [6] and the Quality of Life Questionnaire for Cancer Patients Treated with Anticancer Drugs-Breast (QOL-ACD-B) [14]. The latter three instruments were employed to test the construct validity.

Traditional psychometric analysis

Acceptability, reliability and validity were calculated statistically from the data obtained using SPSS 16.0 Japanese version.

Acceptability Score distribution and missing rates were examined.

Reliability Test–retest reliability was assessed by intraclass correlation coefficient (ICC). Internal consistency, the extent to which items comprising these subscale measures the same concept, was assessed by Cronbach's alpha coefficients (>0.70) and item-total correlation (>0.3) [20].

Construct validity To demonstrate construct validity, evidence that the instrument measures what it purports to measure, convergent and discriminant validity were examined by the multitrait-multimethod (MTMM) approach. For convergent validity, we assessed correlations between the scores in the BREAST-Q and the 3 other instruments (EORTC QLQ-BR23, FACT-B and QOL-ACD-B).

The EORTC QLQ-BR23 is a module of the EORTC Quality of Life Questionnaire intended to measure breast

cancer-specific issues. It has 23 items that form four functional scales and four symptom scales/item: body image, sexual function, sexual enjoyment, future perspective, systemic therapy side effects, breast symptoms, arm symptoms and upset by hair loss. The score for each of the subscales ranges from 0 to 100. Higher scores indicate better function in the functional scales and worse HRQOL in the symptom scales.

FACT-B is a 38-item questionnaire developed to measure the multidimensional HRQOL in patients with breast cancer. The assessment comprises five domains: physical well-being, social/family well-being, emotional well-being, functional well-being and breast cancer subscale (BCS). Among the BCS items, we picked three items as criteria to test construct validity: BCS2 'self-conscious about the way I dress', BCS4 'sexually attractive' and BCS9 'feel like a woman'.

The QOL-ACD-B is a breast cancer-specific instrument designed for use along with the QOL-ACD, which examines the influence of anticancer drugs on patients HRQOL. While developed domestically, the content is feasible with respect to Japanese life style and culture. It is comprised 21 items that form five domains: physical symptom and pain, satisfaction with care and coping with disease, side effects of anticancer drugs, clothing and sexuality, and maternity. The former two domains can be transformed into scores ranging from 0 to 100. Item 15 'feel any inconvenience because you were unable to choose clothes that you wanted to wear?' and Item16 'feel reluctant to disrobe in the presence of other people, such as at a spa?' were highlighted as criteria.

We hypothesized the following: subscales in BREAST-Q and subscales in the other three instruments should exhibit moderate to high correlation ($r > 0.4$) depending on the similarity of constructs being measured by each instruments and the correlations.

1. Satisfaction with the Breast subscale would correlate more to the body image scale of the EORTC QLQ-BR23, item15 and 16 in QOL-ACD-B than to the other scales, and the correlation coefficients would be moderate to strong ($r > 0.4$) because these scales contain many concepts about satisfaction on their breast contours and clothing.
2. The psychosocial well-being subscale would be more correlated to the body image scale in the EORTC QLQ-BR23, functional well-being scale, BCS4 and 9 in FACT-B, item15 and 16 in QOL-ACD-B than to the other scales. These scales contain concepts of patients' self-esteem, femininity and limitation in their daily lives.
3. The physical well-being subscale would correlate moderately to strongly with the breast symptom and arm symptom scales in the EORTC QLQ-BR23, the FACT-B physical well-being scale, and the QOL-ACD-B physical symptom and pain scale because the physical well-being subscale in BREAST-Q is comprised items concerning pain and morbidity in upper extremity and breast.
4. The sexual well-being subscale in BREAST-Q would correlate to the body image and sexual function subscales in the EORTC QLQ-BR23, the BCS4 and 9 in FACT-B, because the sexual well-being subscale in the BREAST-Q is comprised items concerning not only sexual function but also sexual attractiveness.
5. The satisfaction with care subscales (i.e., satisfaction with the surgeon, medical team, and office staff) would correlate with the satisfaction with care and coping with disease scale in the QOL-ACD-B. Common points include the concepts of the relationship with care providers.

For discriminant validity, we also hypothesized that age, BMI (body mass index) and follow up period would not correlate highly ($r < 0.4$) with the BREAST-Q subscale scores.

The protocol received ethical approval from Okayama University Hospital.

Results

Stage I

Forward translation

There were some issues in the forward translation. First, among several items on pain and sensation in the breast region (in the physical well-being subscale in all modules), some were similar and confusing when translated into Japanese. We used much more detailed expressions to allow respondents to distinguish the intended meanings. Second, for item3c in the satisfaction with outcome subscale in the breast reconstruction module, after the sentence 'I would do it again.' We added an annotation '(If I went back in time, I would make the same decision.)' in Japanese to avoid respondents interpreting this question as 'I could go through the same operation once again.' Third, we asked the author to define abdominal bulging concretely and we added the words 'e.g., hernia'.

Backward translation

No crucial differences were found between the back-translated version and the original English version. Therefore, no revisions were made.

Patient testing

The results of patient testing, number of participants, their age and time needed to complete the questionnaire, are shown in Table 2. The reduction module of the BREAST-Q was not tested because there were few patients undergoing reduction and mastopexy surgery in our related hospitals. The average time to complete the postoperative questionnaire for each module was greater than 10 min.

Through the cognitive interview, several issues were pointed out regarding understanding words and phrases, and irregularities of the connections between the questions and the response options, for which adjustments were made to generate the final version of the questionnaire. A sentence indicating the option of 'N/A' was added at the end of the instructions in the sexual well-being subscale to reduce the missing rate.

None of the participants reported that any item represented any issue(s) unrelated to her operation and her disease or condition. This results suggested good content validity of the BREAST-Q Japanese version among Japanese women. However, there were some cultural differences between the original target population and Japanese women as follows: two patients claimed that they were too old to answer the questions about sexuality and another patient said that she was embarrassed at the items asking how often she felt 'attractive', 'sexually attractive' and 'feminine', because she believed it was up to somebody else to evaluate her with respect to her 'attractiveness' and 'femininity'.

The report of patient testing and the final versions were sent to MRT and accepted in 2013. The Japanese version of the BREAST-Q that we developed is now open to the public. It is available from MRT, and can be accessed from the homepage of the original BREAST-Q (https://webcore.mskcc.org/breastq/). The copyright of the respondents' Japanese version also belongs to the Memorial Sloan Kettering Cancer Center and The University of British Columbia.

Stage II

Of 45 women who agreed to participate in the study, 44 (97.8 %) completed the two sets of questionnaires. Demographic and medical characteristics of the respondents are presented in Table 3. The age of the participants was relatively high and only 7 women were under 50 years of age.

Acceptability

The item frequency distribution and missing rate for each item during the first administration are presented in Table 4.

In each item of the sexual well-being subscale, a floor effect was seen. In other words, the response rate to select category 2 (A little of the time) to 5 (All of the time) were very low and most of the respondents selected category 1 (None of the time) or N/A (not applicable). A floor effect was seen for item 2j asking 'how often do you feel you are attractive?' and also for all of the items in the physical well-being subscale. A ceiling effect was observed for all of the items in satisfaction with care domains.

High missing rates were only seen for items 4b and 4d (11.4 %) in the sexual well-being subscale.

Reliability

The average scores for the first and second administration of each subscale in the BREAST-Q, along with the intra-class correlation coefficient (ICC) are shown in Table 5. Overall, good reproducibility was found (>0.7) except for the sexual well-being subscale, in which the response rate was lower.

Internal consistencies were adequate, except for the sexual well-being subscale in which only 7 respondents completed all of the items (Table 6).

Table 2 Patient testing

Module	Preoperative/postoperative questionnaire	*N*	Age average (range)	Time to completion (min) average (range)	Number of items
Mastectomy	Pre	5	51.8 (32–70)	4.2 (3–6)	36
	Post	5	56.6 (37–74)	12.4 (10–16)	62
Reconstruction	Pre	5	40.2 (30–50)	5.6 (4–9)	42
	Post	5	52.8 (44–65)	12.2 (6–20)	116
Augmentation	Pre	5	43 (24–59)	3.4 (2–5)	25
	Post	6	35.8 (24–59)	13.0 (11–15)	88

Total number of items includes all optional items

Table 3 Demographic and medical characteristics of the respondents ($N = 44$)

Characteristics	*N*	%	Characteristics	*N*	%
Age at participation			Follow up period (months)		
Mean (range)	61.8 (40−80)		Mean	48.1	
Age group			Range	8.0–209.3	
<50	7	15.9	Clinical stage at diagnosis		
50–69	24	54.5	0	3	6.8
70 and older	13	29.5	I	12	27.3
BMI			II	17	38.6
Mean (range)	23.5 (17.4−37.8)		III	8	18.2
Marital status			IV	1	2.3
Single	4	9.1	Unknown	3	6.8
Married	28	63.6	Pathological nodal involvement		
Divorced	2	4.5	Positive	29	43.2
Widowed	10	22.7	Negative	15	34.1
Education			Received adjuvant radiotherapy		
High school or less	28	63.6	No	35	79.5
College education	15	34.1	Yes	9	20.5
Unknown	1	2.3	Received adjuvant chemotherapy		
Employment status			No	17	38.6
Not working	26	59.1	Yes	27	61.4
Working	18	41.0	Received adjuvant endocrine therapy		
Household income (JPY)			No	8	18.2
<5,000,000[a]	26	59.1	Yes	36	81.8
5,000,000– 10,000,000	14	31.8	Laterality of mastectomy		
>10,000,000[b]	1	2.3	Unilateral	42	95.5
Unknown	3	6.8	Bilateral	2	4.5
Concomitant disease			Preceding lumpectomy		
None	19	43.2	No	42	95.5
Hypertension	9	20.5	Yes	2	4.5
Other malignant tumor	8	18.2			
Diabetes mellitus	4	9.1			
Others	12	27.3			

JPY Japanese yen

[a] $41,700, [b] $83,300 at an exchange rate of 120 JPY per US Dollar

Convergent and discriminant validity

The correlation coefficients between the BREAST-Q and the EORTC QLQ-BR23, FACT-B and QOL-ACD-B are shown in Table 7. Our hypotheses were almost all confirmed, except for the following two findings. Correlations between the sexual well-being subscale in the BREAST-Q and the body image scale and sexual function scale in the EORTC QLQ BR23 were not significant. The functional well-being subscale in FACT-B exhibited as strong a correlation as the body image scale in the EORTC QLQ BR23 to the satisfaction with breast subscale in the BREAST-Q.

The correlations between age, BMI, follow up period and the BREAST-Q subscales were less than 0.32, which supports the hypothesized convergent validity.

Discussion

Objective assessments, such as rating beauty, measurement of symmetry and investigating complication rates are insufficient as outcomes of breast surgery because body image issues can have a great impact on the HRQOL and patient satisfaction [24–26]. There are some outcomes that only appear in patients' daily lives and their minds; the fit of bras, limitations in clothing, self-confidence in public events, coping with disease, etc. PRO measures play an important role in providing us with these subjective outcomes.

The BREAST-Q is a validated PRO measure to assess the impact of breast surgery on patient satisfaction and HRQOL. One of its advantages is its usefulness in routine clinical practice because it was constructed based on the

Table 4 Item frequency distribution and missing in percentage (%) ($N = 44$)

Subscale item	Response category					Missing	Subscale item	Response category						Missing
	1	2	3	4	5			1	2	3	4	5	N/A	
Satisfaction with breast							Sexual well-being							
1a	6.8	40.9	38.6	13.6	–	0.0	4a	50.0	11.4	4.5	0.0	2.3	29.5	2.3
1b	18.2	29.5	34.1	11.4	–	6.8	4b	9.1	4.5	4.5	0.0	0.0	70.5	11.4
1c	29.5	40.9	20.5	4.5	–	4.5	4c	36.4	0.0	0.0	0.0	0.0	56.8	6.8
1d	47.7	31.8	11.4	4.5	–	4.5	4d	9.1	2.3	2.3	2.3	0.0	72.7	11.4
							4e	56.8	0.0	0.0	0.0	0.0	38.6	4.5
Psychosocial well-being							4f	56.8	0.0	0.0	0.0	0.0	38.6	4.5
2a	34.1	13.6	22.7	18.2	9.1	2.3								
2b	4.5	20.5	25.0	20.5	29.5	0.0	Satisfaction with surgeon							
2c	6.8	6.8	34.1	25.0	27.3	0.0	5a	4.5	2.3	13.6	79.5	–	–	0.0
2d	29.5	25.0	15.9	15.9	13.6	0.0	5b	6.8	13.6	29.5	50.0	–	–	0.0
2e	27.3	20.5	25.0	13.6	13.6	0.0	5c	2.3	2.3	29.5	65.9	–	–	0.0
2f	25.0	27.3	27.3	13.6	6.8	0.0	5d	6.8	9.1	22.7	61.4	–	–	0.0
2g	0.0	13.6	18.2	29.5	38.6	0.0	5e	4.5	0.0	25.0	70.5	–	–	0.0
2h	18.2	18.2	18.2	25.0	18.2	2.3	5f	6.8	2.3	22.7	68.2	–	–	0.0
2i	25.0	18.2	20.5	20.5	15.9	0.0	5g	4.5	11.4	29.5	52.3	–	–	2.3
2j	61.4	13.6	15.9	2.3	6.8	0.0	5h	4.5	6.8	22.7	65.9	–	–	0.0
							5i	2.3	6.8	22.7	68.2	–	–	0.0
Physical well–being							5j	2.3	9.1	18.2	70.5	–	–	0.0
3a	56.8	13.6	20.5	6.8	2.3	0.0	5k	2.3	6.8	36.4	52.3	–	–	2.3
3b	54.5	15.9	20.5	9.1	0.0	0.0	5l	2.3	11.4	36.4	47.7	–	–	2.3
3c	36.4	13.6	25.0	13.6	11.4	0.0								
3d	43.2	13.6	29.5	13.6	0.0	0.0	Satisfaction with medical team							
3e	56.8	25.0	13.6	4.5	0.0	0.0	6a	2.3	6.8	31.8	59.1	–	–	0.0
3f	36.4	38.6	20.5	2.3	2.3	0.0	6b	0.0	4.5	36.4	59.1	–	–	0.0
3g	65.9	18.2	11.4	0.0	4.5	0.0	6c	0.0	6.8	29.5	63.6	–	–	0.0
3h	70.5	20.5	9.1	0.0	0.0	0.0	6d	0.0	2.3	22.7	75.0	–	–	0.0
3i	56.8	15.9	13.6	4.5	9.1	0.0	6e	0.0	2.3	34.1	63.6	–	–	0.0
3j	61.4	20.5	6.8	6.8	4.5	0.0	6f	0.0	9.1	34.1	54.5	–	–	2.3
3k	70.5	20.5	2.3	4.5	2.3	0.0	6 g	0.0	4.5	40.9	52.3	–	–	2.3
3l	75.0	15.9	2.3	4.5	2.3	0.0								
3m	88.6	9.1	2.3	0.0	0.0	0.0	Satisfaction with office staff							
3n	86.4	11.4	2.3	0.0	0.0	0.0	7a	0.0	15.9	31.8	52.3	–	–	0.0
3o	75.0	15.9	6.8	2.3	0.0	0.0	7b	0.0	9.1	47.7	43.2	–	–	0.0
3p	86.4	6.8	6.8	0.0	0.0	0.0	7c	0.0	11.4	40.9	47.7	–	–	0.0
							7d	0.0	9.1	43.2	47.7	–	–	0.0
							7e	2.3	9.1	40.9	47.7	–	–	0.0
							7f	0.0	18.2	34.1	47.7	–	–	0.0
							7g	2.3	13.6	38.6	43.2	–	–	2.3

N/A Not applicable

Rasch measurement model. It is the first surgery-specific instrument in the area of breast oncology, covering three major procedures: mastectomy, breast conserving therapy and breast reconstruction. The BREAST-Q has already been translated into 25 languages. One of the limitations of the BREAST-Q is that it was developed with the North American population in mind, and cultural harmonization has not been achieved in the translation and cultural adaptation process of each module; thus, the validity of the translated version and international comparability is not certain [27]. We developed the BREAST-Q Japanese version in an internationally recognized manner to maintain

Table 5 Test–retest reliability (intraclass correlation coefficient)

Subscale	*N*	First administration		Second administration		ICC	*p* value
		M	SD	*M*	SD		
Satisfaction with breast	43	42.3	16.5	40.4	14.0	0.76	n.s
Psychosocial well-being	43	49.0	19.2	48.3	18.1	0.95	n.s
Physical well-being	42	76.1	15.4	77.1	16.3	0.90	n.s
Sexual well-being	23	9.3	12.4	11.8	14.3	0.67	n.s
Satisfaction with surgeon	43	77.9	21.1	76.0	21.1	0.92	n.s
Satisfaction with medical team	43	81.1	20.6	80.1	20.2	0.88	n.s
Satisfaction with office staff	43	74.7	24.3	75.4	22.8	0.80	n.s

n.s > 0.05

Table 6 Internal consistency

Subscale	No. of item	*N*	Chronbach's α	Item-total correlation	
				Mean	Range
Satisfaction with Breast	4	40	0.77	0.57	0.47–0.69
Psychosocial Well-being	10	43	0.94	0.75	0.62–0.84
Physical Well-being	16	44	0.92	0.65	0.53–0.77
Sexual Well-being	6	7	0.44	0.21	0–0.78
Satisfaction with Surgeon	12	43	0.97	0.85	0.76–0.93
Satisfaction with Medical Team	7	42	0.95	0.85	0.77–0.92
Satisfaction with Office Staff	7	43	0.98	0.92	0.83–0.96

linguistic and conceptual equivalence, and furthermore, tested the psychometric properties of the mastectomy module among Japanese women with breast cancer [20, 21, 23, 28, 29].

In the development stage of the Japanese version, we found an insoluble cultural difference between the original target population and Japanese women with respect to attitudes toward sexuality. One of our participants noted that Japanese women tend to be somewhat shy to talk about their sexuality and modest in expressing their attractiveness, while two others insisted that they were too old to answer the questions about sexuality.

Previous studies about cultural difference in sexuality have reported [30–33] that Asian women were more likely to have suppressive sexual attitudes and endorse beliefs of sexual behavior being more oriented toward reproduction [30]. Transformation of sense of self and sexuality with age also varies between different cultures. In a cross-national survey of senior sexuality involving 27,500 men and women in 29 countries, subjective sexual well-being, referring to physical and emotional satisfaction in relationships with the partner, were the lowest in Japan [31]. It has also been reported that from the perspective of elderly Japanese women, sexual relationships were not important in later life [32].

However, in regards to content validity, this does not mean that the sexual well-being subscale is not suitable for Japanese woman as we found that none of our participants claimed these issues were unrelated to their disease and operation. As reported by Takahashi and Kai, although research on sexuality and cancer in Japan is scarce, Japanese breast cancer survivors do have troubles in their sexual relationship with partners as a consequence of breast cancer treatment [34]. Therefore, we medical providers should take measures to deal with these issues [35]. We considered that the BREAST-Q sexual well-being subscale is an important domain that could be key to better understanding how Japanese woman would be affected by breast surgeries.

In psychometric testing of the mastectomy module, good reliability and validity were demonstrated for the satisfaction with breast subscale, the psychosocial well-being subscale, the physical well-being subscale and the satisfaction with care subscales but only for the sexual well-being subscale. Given the cultural differences in attitudes toward sexuality and higher age of our sample population, it is considered natural that missing rates were high and ceiling effects were seen in the sexual well-being subscale, which should lead to a lower score and reduce the internal consistency. As a result of convergent validity, the sexual well-being subscale is more related to sexual attractiveness and sense of femininity than to sexual function in our elderly participants. These traditional psychometric properties are sample dependent. Therefore,

Table 7 Convergent and discriminant validity (Pearson's *r*)

Scale/item	BREAST-Q						
	Satisfaction with breast	Psychosocial well-being	Physical well-being	Sexual well-being	Satisfaction with surgeon	Satisfaction with medical team	Satisfaction with office staff
EORTC QLQ							
BI	0.49**	0.54**	0.24	0.21	0.29	0.14	0.12
BS	−0.28	−0.30	−0.61**	−0.13	−0.14	−0.27	−0.17
AS	−0.29	−0.41**	−0.63**	−0.20	−0.07	0.00	0.05
SF	−0.04	−0.14	0.13	0.32	−0.03	0.04	−0.07
FACT-B							
PWB	0.25	0.40**	0.58**	0.19	0.20	0.10	−0.04
SWB	0.37*	0.35*	0.14	0.16	0.37*	0.47**	0.40**
EWB	0.39**	0.46**	0.39**	0.28	0.11	0.03	0.10
FWB	0.50**	0.52**	0.32*	0.29	0.18	0.11	0.00
BCS4	0.39*	0.70**	0.29	0.75**	0.11	0.02	0.11
BCS9	0.24	0.51**	0.12	0.47**	0.11	0.08	0.20
QOL-ACD							
PSP	0.35*	0.42**	0.51**	0.14	0.19	0.14	0.04
SC/CD	0.42**	0.35*	0.31*	0.05	0.65**	0.73**	0.60**
Item15	0.56**	0.58**	0.01	0.31	0.18	0.05	0.09
Item16	0.56**	0.58**	0.01	0.31	0.18	0.05	0.09
Age	−0.02	0.24	−0.09	0.00	0.34*	0.06	0.23
BMI	−0.26	−0.08	−0.11	0.09	0.03	0.05	0.12
Follow up period	−0.24	−0.21	0.06	0.07	−0.15	−0.03	−0.04

EORTC QLQ European Organization for Research and Treatment of Cancer B23, *BI* Body Image, *BS* Breast Symptom, *AS* Arm Symptom, *SEF* Sexual Functioning, *FACT* Functional Assessment of Cancer Therapy-Breast, *SWB* Social/Family Well-being, *EWB* Emotional Well-being, *FWB* Functional Well-being, *PWB* Physical Well-being, *BCS* Breast Cancer Subscale, *BCS4* 'sexually attractive', *BCS9* 'feel like a woman', *QOLACD* Quality of Life Assessment of Cancer Patients receiving Chemotherapy-Breast, *PSP* Physical symptom and pain, *SC/CD* Satisfaction with Care and Coping with disease, Item15 'feel any inconvenience because you were unable to choose clothes that you wanted to wear?', Item16 'feel reluctant to disrobe in the presence of other people, such as at spa?', *BMI* Body Mass Index

* $p < 0.05$, ** $p < 0.01$

further investigations in younger samples are needed to examine the scale function of the sexual well-being subscale. Currently, a study to assess the psychometric properties of the BREAST-Q reconstruction module is in progress, which includes the participation of younger women with breast cancer. We are also considering re-evaluating the validity and reliability of the BREAST-Q Japanese version using Rasch analysis.

Despite the fact that we could not reveal sufficient validity and reliability in this study, we do not consider that the sexual well-being subscale should be excluded in the mastectomy module, as the aim of this project, to develop a Japanese version of the BREAST-Q, is to establish a new universal standard instrument without negating the construction of the original one. Furthermore, it would also be beneficial to include the sexual well-being subscale in the mastectomy module rather than excluding it in future studies involving younger populations, i.e., concerning fertility.

Since the international comparability of the BREAST-Q has not been proven, it remains difficult to aggregate the international outcomes. According to previous studies, the sexual well-being score of our sample was much lower compared with the reports from Western countries, in which the mean score were reported about 37.8–49.4 in post-mastectomy or pre-delayed breast reconstruction women [36–38], while scores in the other subscales were virtually equivalent. Reports from Asian countries remain limited: Huang et al. [39] reported that the sexual well-being subscales scores were 11.5 preoperatively and 19.2 postoperatively (3 months) in six consecutive patients who underwent simultaneous unilateral breast reconstruction

and contralateral breast augmentation using DIEP flap; they also reported a lower level of sexual well-being compared with the Western women. These findings suggest that the level of sexual well-being is lower in Asian women, which is consistent with the findings of previous studies; however, we must remain cognizant that the Western conceptualized measure is not sufficiently capable to capture the sexuality of Asian women.

In term of respondent burden [20], which can influence the patients' responses to questionnaires, the BREAST-Q has rather a large number of items, which led to average time for completion exceeding 10 min. Questions about sexuality could also increase the psychological burden among the Japanese population. We must consider these respondent burdens, especially in routine clinical application of the BREAST-Q. One solution is to omit unnecessary subscales depending on the purpose of the investigation. This could be possible since the BREAST-Q subscales function independently [19]. Providing private space and caring for individual patients' physical and psychological states are also important in reducing respondent burden.

In this study, to analyze the psychometric aspects of the BREAST-Q Japanese version, physically and psychologically stable patients were selected to assess reproducibility. Thus, biases exist in the patients' responses to items in the physical well-being subscales. It is considered that ceiling effects in the satisfaction with care subscales are due to the study design, as it was performed in a single institution, questionnaires were handed to the patients by the medical staff and sent back to their hospital. Development of the Japanese versions of the newly published BCT module, expectation module and LD scale is currently in progress. We are also conducting a longitudinal study to examine the sensitivity and minimally important difference of the BREAST-Q Japanese version.

Conclusion

We developed Japanese versions of the BREAST-Q mastectomy module, reconstruction module, augmentation module and reduction/mastopexy module. Psychometric tests of the mastectomy module among Japanese women with breast cancer showed good reliability and validity, except for the sexual well-being subscale, which could be because of the older age of the study participants, as well as underlying cultural differences of attitudes toward sexuality between Japanese women and original target population. Although further examination is necessary for the scale function of the sexual well-being subscale, we consider it to be an important domain in better understanding how Japanese breast cancer survivors are affected by mastectomy.

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Complicance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Shimozuma K, Ganz PA, Petersen L, Hirji K. Quality of life in the first year after breast cancer surgery: rehabilitation needs and patterns of recovery. Breast Cancer Res Treat. 1999;56:45–57.
2. Ganz PA, Desmond KA, Leedham B, Rowland JH, Meyerowitz BE, Belin TR. Quality of life in long-term, disease-free survivors of breast cancer: a follow-up study. J Natl Cancer Inst. 2002;94:39–49.
3. Ware JJ, Sherbourne C. The MOS 36-item short-form health survey (SF-36) I conceptual framework and item selection. Med Care. 1992;30:473–83.
4. Sprangers MA, Groenvold M, Arraras JI, Franklin J, te Velde A, Muller M, et al. The European organization for research and treatment of cancer breast cancer-specific quality of life questionnaire module: first results from a three-country field study. J Clin Oncol. 1996;14:2756–68.
5. Aaronson NK, Ashmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The EORTC QOL-C30: a quality of life instrument for use in international clinical trials in oncology. J Natl Cancer Inst. 1993;85:365–76.
6. Brady MJ, Cella DF, Mo F, Bonomi AE, Tulsky DS, Lloid SR, et al. Reliebility and validity of the functional assessment of cancer therapy-breast quality-of-life instrument. J Clin Oncol. 1997;15:974–86.
7. Housheer FH, Schilsky RL, Brain S, Berghorn EJ, Lieberman F. Diagnosis, management, and evaluation of chemotherapy-induced peripheral neuropathy. Semin Oncol. 2006;33:15–49.
8. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the hospital anxiety and depression scale. An updated literature review. J Psychosom Res. 2002;52:69–77.
9. Hurst NP, Kind P, Ruta D, Hunter M, Stubbings A. Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of EuroQol (EQ-5D). Br J Rheumatol. 1997;36:551–9.
10. Ohsumi S, Shimozuma K. Current status and future perspectives of patient-reported outcome research in clinical trials for patients with breast cancer in Japan. Breast Cancer. 2013;20:296–301.
11. Takei H, Ohsumi S, Shimozuma K, Takehara M, Suemasu K, Ohashi Y, et al. Health-related quality of life psychological distress, and adverse events in postmenopausal women with breast cancer who receive tamoxifen, exemestane, or anastrozole as adjuvant endocrine therapy: national surgical adjuvant study of breast cancer 04 (N-SAS BC 04). Breast Cancer Res Treat 2012;133:227–36.
12. Shimozuma K, Ohashi Y, Takeuchi A, Aranishi T, Morita S, Kuroi K, et al. Feasibility and validity of the patient neurotoxicity questionnaire during taxane chemotherapy in a phase III

randomized trial in patients with breast cancer: N-SAS BC 02. Support Care Cancer. 2009;17:1483–91.
13. Taira N, Shimozuma K, Shiroiwa T, Ohsumi S, Kuroi K, Saji S, et al. Associations among baseline variables, treatment-related factors and health-related quality of life 2 years after breast cancer surgery. Breast Cancer Res Treat. 2011;128:735–47.
14. Kurihara M, Shimizu H, Tsuboi K, Kobayashi K, Mutakami M, Eguchi K, et al. Development of quality of life questionnaire in Japan: quality of life assessment of cancer patients receiving chemotherapy. Psycho-Oncol. 1999;8:355–63.
15. Wilkins EG, Cedema PS, Lowery JC, Davis JA, Kim HM, Roth RS, et al. Prospective analysis of psychosocial outcomes in breast reconstruction: one-year postoperative results from the Michigan breast reconstruction outcome study. Plas Reconstr Surg. 2000;106:1014–25.
16. Baxter NN, Goodwin PJ, McLeod RS, Dion R, Devins G, Bombardier C. Reliability and validity of the body image after breast cancer questionnaire. Breast J. 2006;12:221–32.
17. Pusic AL, Klassen AF, Scott AM, Klok JA, Cordeiro PG, Cano SJ. Development of a new patient-reported outcome measure for breast surgery: the BREAST-Q. Plast Reconstr Surg. 2009;124:345–53.
18. Cano SJ, Klassen AF, Scott AM, Cordeiro PG, Pusic AL. The BREAST-Q: further validation in independent clinical samples. Plast Reconstr Surg. 2012;129:293–302.
19. Cano SJ, Klassen AF, Scott AM, Pusic AL. A closer look at the BREAST-Q. Clin Plast Surg. 2013;40:287–96.
20. U.S. department of health and human services FDA center for drug evaluation and research, U.S. department of health and human services FDA center for biologics evaluation and research, U.S. department of health and human services FDA center for devices and radiological health. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. Health Qual Life Outcomes. 2006;4:79. doi:10.1186/1477-7525-4-79.
21. Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, Perrin E, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res. 2002;11:193–205.
22. Rasch G. Probabilistic models for some intelligence and attainment tests. Copenhagen: The danish institute for educational research; 1960.
23. Acquadro C, Conway K, Giroudet C, Mear I. Linguistic validation manual for health outcome assessments. Lyon: MAPI institute; 2012.
24. Reich M, Lesur A, Perdrizet-Chevallier C. Depression, quality of life and breast cancer: a review of the literature. Breast Cancer Res Treat. 2008;110:9–17.
25. Cororve GM, Teo I, Epner DE. Managing body image difficulties of adult cancer patients. Cancer. 2014;120:633–41.
26. Reaby LL. Reasons why women who have mastectomy decide to have or not to have breast reconstruction. Plast Reconstr Surg. 1988;101:1810–8.
27. Kanatas A, Velikova G, Roe B, Horgan K, Ghazali N, Shaw RJ, et al. Patient-reported outcomes in breast oncology: a review of validated outcome instruments. Tumori. 2012;98:678–88.
28. Acquadro C, Conway K, Hareendran A, Aaronson N. European regulatory issues and quality of life assessment (ERIQA) group. Literature review of methods to translate health-related quality of life questionnaires for use in multinational clinical trials. Value Health. 2008;11:509–21.
29. Wild D, Grove A, Mrtin M, Eremenco S, Verjee-Lorenz A, Erikson P. ISPOR task force for translation and cultural adaptation. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health. 2005;8:94–104.
30. Morton H, Gorzalka BB. Cognitive aspects of sexual functioning: differences between East Asian-Canadian and Euro-Canadian women. Arch Sex Behav. 2013;42:1615–25.
31. Laumann EO, Palk A, Glasser DB, Kang JH, Wang T, Levinson B, et al. A cross-national study of subjective sexual well-being among older women and men: findings from the Global Study of Sexual Attitudes and Behaviors. Arch Sex Behav. 2006;35:145–161.
32. Cain VS, Johannes CB, Avis NE, Mohr B, Schocken M, Skurnick J, et al. Sexual functioning and practices in a multi-ethnic study of midlife women: baseline results from SWAN. J Sex Res. 2003;40:266–76.
33. Moore KL. Sexuality and sense of self in later life: Japanese men's and women's reflections on sex and aging. J Cross Cult Gerontol. 2010;25:149–63.
34. Takahashi M, Kai I. Sexuality after breast cancer treatment: changes and coping strategies among Japanese survivors. Soc Sci Med. 2005;61:1278–90.
35. Takahashi M, Kai I, Hisata M, Higashi Y. Attitudes and practices of breast cancer consultations regarding sexual issues: a nationwide survey of Japanese surgeons. J Clin Oncol. 2006;24:5763–8.
36. Rosson GD, Shridharani SM, Magarakis M, Manahan MA, Basdag B, Gilson MM, et al. Quality of life before reconstructive breast surgery: a preoperative comparison of patients with immediate, delayed, and major revision reconstruction. Microsurgery. 2013;33:253–8.
37. Zhong T, McCarthy C, Min S, Zhang J, Beber B, Pusic AL, et al. Patient satisfaction and health-related quality of life after autologous tissue breast reconstruction: a prospective analysis of early postoperative outcomes. Cancer. 2012;118:1701–9.
38. Eltahir Y, Werners LL, Dreise MM, van Emmichoven IA, JansenL Werker PM, et al. Quality-of-life outcomes between mastectomy alone and breast reconstruction: comparison of patient-reported BREAST-Q and other health-related quality-of-life measures. Plast Reconstr Surg. 2013;132:201e–9e.
39. Huang JJ, Chao LF, Wu CW, Nguyen DH, Valerio IL, Cheng MH. Simultaneous scarless contralateral breast augmentation during unilateral breast reconstruction using bilateral differentially split DIEP flaps. Plast Reconstr Surg. 2011;28:593e–604e.