Initial experience of the BREAST-Q breast-conserving therapy module

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Introduction

Assessment of patient-reported outcome measures (PROMs) after surgery has become an important end-point in clinical trials. Tools in the form of questionnaires are vital for evaluating new treatments and procedures as well as providing important metrics for a surgeon or unit to document and audit their clinical performance. Moreover, repeated evaluation allows recognition of changes in patients' needs that require input from their medical team.

The BREAST-Q is a questionnaire developed at the Memorial Sloan-Kettering Cancer Center, USA, to elicit and quantify patient perception of outcomes after breast surgery (https://webcore.mskcc.org/breastq) [1]. It has been developed using extensive patient input and Rasch psychometric methods [2, 3], to measure patient satisfaction and quality of life. Modules have been developed for patients undergoing mastectomy, breast reconstruction, augmentation, reduction/mastopexy and most recently breast-conserving therapy (BCT, wide local excision and radiotherapy). This module contains five domains that cover satisfaction with breasts, effect of radiotherapy, physical, psychological and sexual wellbeing. There are also four domains that focus on satisfaction with the information provided and staff interactions. Within each domain, the patient answers multiple sub-questions according to a Likert scale. To date, there have been nearly one hundred publications using the BREAST-Q as an outcome measure. Prior to the BCT module being available, researchers modified one of the other modules to make it relevant to BCT patients [4], but this strategy did not address all the relevant issues.

To date, there is only one other published study utilising the official BREAST-Q BCT module questionnaire, a comparison of the 'Satisfaction with breasts' domain in patients undergoing BCT with those undergoing mastectomy with or without reconstruction. This study demonstrated that women who underwent abdominal, buttock or thigh flap reconstruction reported a higher breast satisfaction score than those who underwent breast conservation, and women who underwent implant reconstruction had the lowest satisfaction [5]. The mean or median scores for each of the other domains of the BREAST-Q BCT module were not presented in this study.

The primary aim of our study was to investigate patient satisfaction and quality of life after unilateral BCT using the BREAST-Q BCT module. We also sought to identify clinical risk factors for women being less satisfied with their breast after surgery as reported in the 'Satisfaction with breasts' domain, and to assess the correlation between the 'Satisfaction with breasts' domain and the other domains within the BREAST-Q BCT module.

Methods

Study population

Research ethical committee approval was obtained (ClinicalTrials.gov Identifier: NCT02304614). Women aged ≥18 years who had undergone BCT for an invasive or in situ carcinoma between 1 and 6 years before the start of the study met the inclusion criteria. Patients who had developed recurrent (local or distant) disease since BCT were excluded, as were those who had previously or subsequently had surgery to the index or contralateral breast and those unable to complete the questionnaire due to learning difficulties or a language barrier.

Eligible patients with mammograms scheduled at a time when the lead investigator of the study (ROC) was available to obtain informed consent were identified from the hospital database of surveillance mammogram bookings. Patients were invited to participate in the study by letter. The participants completed the questionnaire anonymously in paper format in a quiet room after their planned surveillance mammogram and returned the completed questionnaire to an independent member of staff.

Clinicopathological data were collected from the hospital electronic patient record into an electronic case report form. Results from the questionnaire were entered into an excel spread sheet (Microsoft Corp., Redmond, Washington) independent of the collection of clinicopathological data.

Data analysis

Scores were derived for each of the questionnaire's nine domains. These were transformed on a scale of 0–100 according to the BREAST-Q protocol, with a higher value representing a more favourable outcome. Analysis was undertaken using SPSS (SPSS v22; SPSS, Inc., Chicago). Descriptive statistics used included the mean/standard deviation and

median/interquartile range for parametric and non-parametric data, respectively.

Univariate linear regression analysis was used to identify clinicopathological variables which were associated with the ‘Satisfaction with breasts’ score. Variables with a *p* value of less than 0.1 were entered into a multivariate model in a forward stepwise manner with a 5 % significance level to identify any independent risk factors.

After testing for normality, Spearman’s rho correlation coefficients were calculated between ‘Satisfaction with breasts’ scores and all other domains. These were tested with a two-sided 5 % significance level.

Results

Patient characteristics

Between 01/04/2015 and 31/10/2015, 649 women were scheduled to have a surveillance mammogram. Three hundred and forty two (52.7 %) women were eligible for recruitment to the study and had a mammogram booked at a time when the investigator was available. All were invited but 109 were not contactable by phone to confirm participation. Of the 233 women who were contactable, 206 (88.4 %) agreed to participate and 27 (11.6 %) declined. Six women who agreed to participate did not attend for their mammogram as planned and therefore did not complete the questionnaire. In total, 200 women completed the questionnaire (Fig. 1).

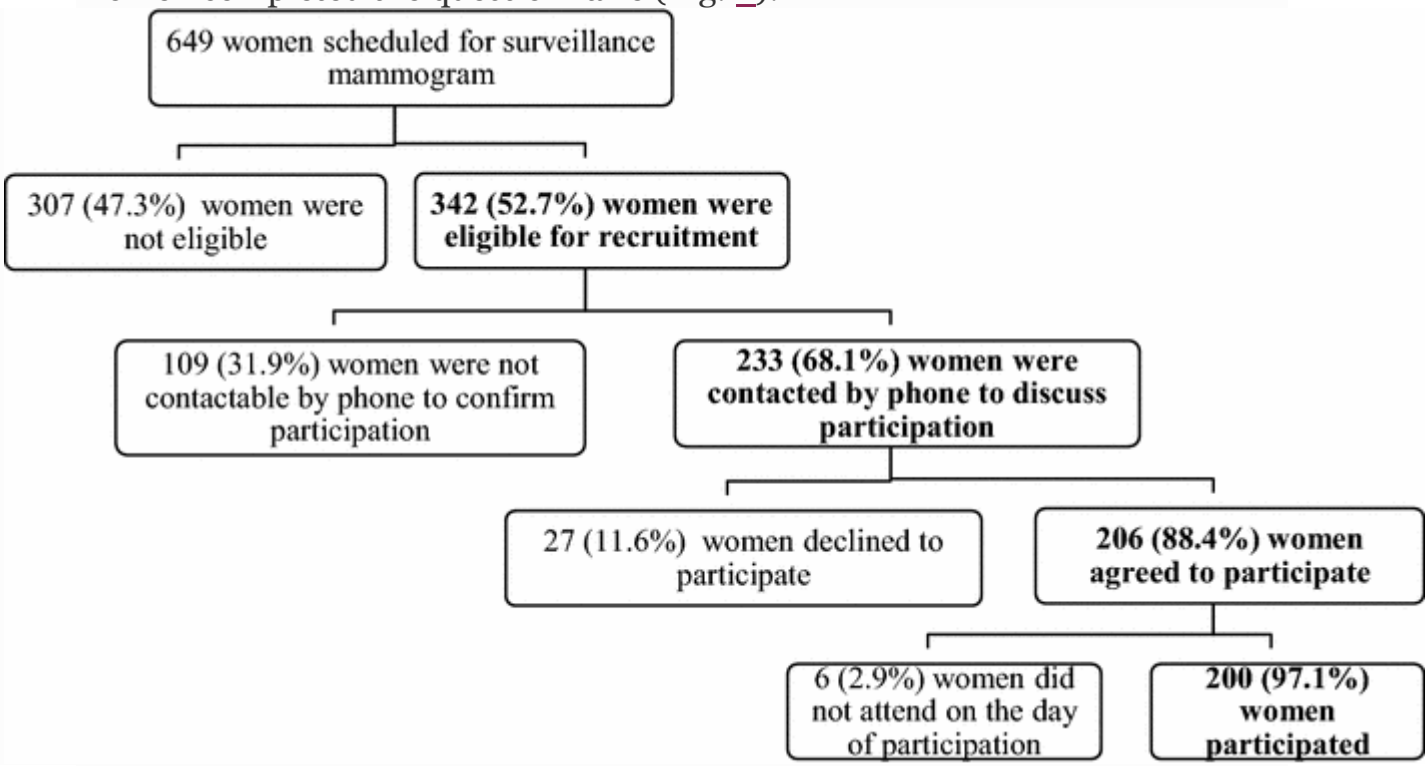


Fig. 1

Recruitment to study

The mean age at time of study was 64.2 years (SD 10.1). 186 women (93 %) were of white British origin. The mean body mass index (BMI) was 27.5 kg/m^2 (SD 5.4). Mean time from breast cancer surgery to participation in the study was 35.4 months (SD 17.7). Mean ultrasound and mammogram

sizes were 13.9 mm (SD 8.6) and 16.3 mm (SD 10.88), respectively. Median surgical pathology specimen weight was 32.5 g (IQR 20–49). Median time from surgery to radiotherapy was 77 days (IQR 66–99.5).

Patient satisfaction and quality of life after undergoing unilateral BCT as reported by the BREAST-Q BCT module

The scores for each domain within the BREAST-Q BCT module are summarised in Table 1. The highest scoring domains were 'Satisfaction with breast surgeon', 'Satisfaction with members of medical team' and 'Satisfaction with members of office staff', all scoring a median of 100 (IQR 100–100). The lowest scoring domain was 'sexual wellbeing', median score 57 (IQR 45–66).

Table 1
Results of BREAST-Q BCT module

Question	Number of participants who replied to question (*n*)	Median (IQR)	Mean (SD)[a]
Satisfaction with breasts	200	68 (55–80)	69 (20)
Effect of radiotherapy	200	89 (78.25–100)	84 (22)
Psycho-social wellbeing	199	82 (63–100)	78 (22)
Sexual wellbeing	125	57 (45–66)	56 (21)
Physical wellbeing	196	75 (64–86)	76 (18)
Satisfaction with information	196	77 (64–100)	77 (22)
Satisfaction with breast surgeon	197	100 (100–100)	91 (18)
Satisfaction with other members of medical team	199	100 (100–100)	93 (20)
Satisfaction with other members of office staff	197	100 (100–100)	94 (19)

[a]All of the results were distributed non-parametrically; however, mean and SD are displayed to allow comparison with other published literature where the mean and SD have been stated

The median score for Domain 1, 'Satisfaction with breasts', was 68 (IQR 55–80). This was reviewed in more depth by plotting the results for each sub-question within the domain (Fig. 2).

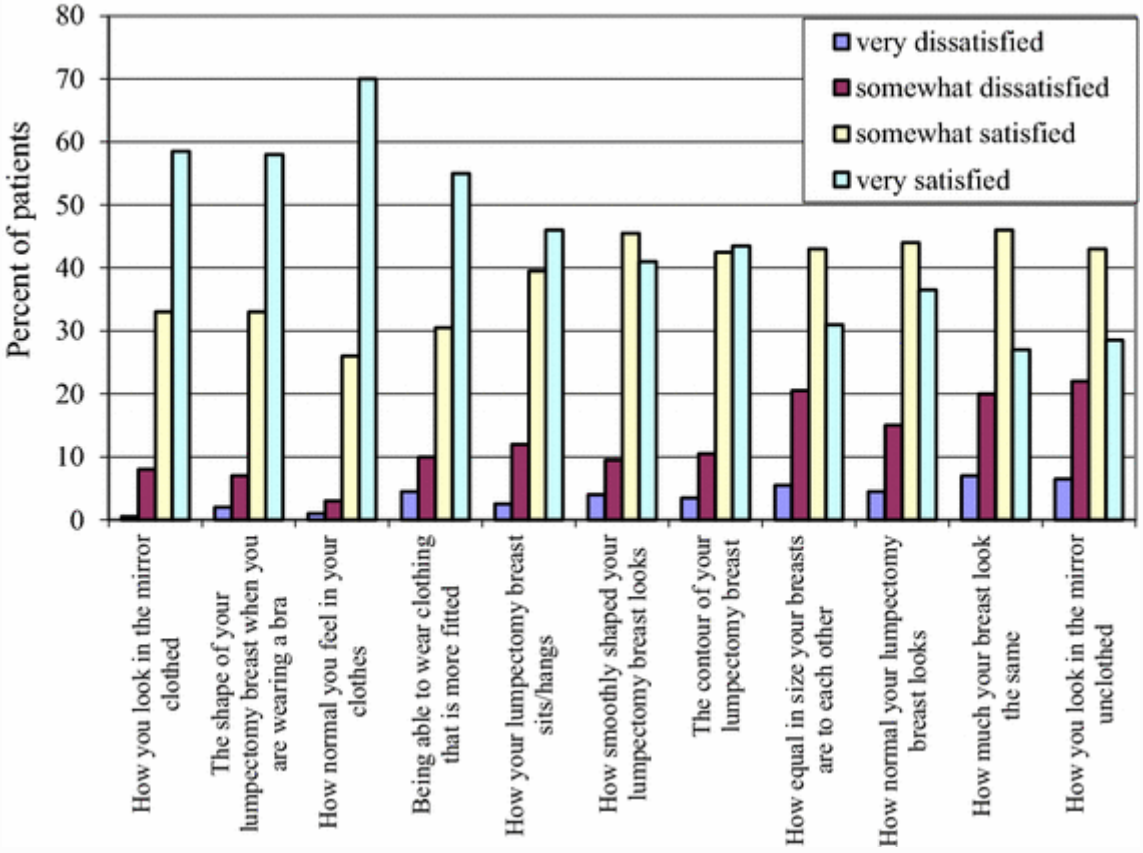


Fig. 2

Answers to the sub-questions of the 'Satisfaction with breasts' domain. Participants answered each sub-question using a Likert scale of very dissatisfied to very satisfied

Identification of clinical risk factors for women being less satisfied with their breasts after surgery as reported in the 'Satisfaction with breasts' domain

Table 2 shows the clinicopathological features entered into the univariate analysis to evaluate risk factors for lower 'Satisfaction with breasts'. BMI at the time of surgery, change in BMI since surgery, type of axillary surgery, nodal status, size of tumour on ultrasound (mm), weight of specimen (*g*) and

delayed wound healing (>30 days) were risk factors ($p < 0.05$) for lower satisfaction on univariate analysis. BMI at the time of surgery, type of axillary surgery and delayed wound healing remained independently risk factors on multivariate analysis (Table 3).

Table 2
Univariate linear regression analyses of 'Satisfaction with breasts' from the BREAST-Q BCT module

Variable	*N*	Constant (95 % CI)	Coefficient (95 % CI)	*p*value
Pre-operative data				
Age at surgery (years)	200	69.8 (55.10–84.56)	0.00 (−0.24 to 0.25)	0.974
Ethnic origin		69.8 (67.1–72.6)		
White	186			
Non-white	14		3.70 (−14.10 to 6.70)	0.483
Smoking status		70.2 (66.7–73.6)		
Never	119			
Current	16		1.02 (−8.98 to 11.03)	0.840
Ex-smoker	65		−2.02 (−7.82 to 3.78)	0.493
Overall				**0.742**
BMI at surgery	196	92.3 (76.8–105.8)	−0.83 (−1.31 to 0.35)	**0.001***
Change in BMI from surgery	187	93.2 (79.5–106.8)	0.84 (0.35 to 1.33)	**0.001***
Location of tumour on pre-op imaging		68.7 (65.1–72.2)		
Upper Outer	109			
Central	8		−2.03 (−15.78 to 11.73)	0.772
Lower inner	27		1.64 (−6.42 to 9.72)	0.688
Lower outer	21		7.59 (−1.36 to 16.54)	0.096

Variable	*N*	Constant (95 % CI)	Coefficient (95 % CI)	*p*value
Upper Inner	35		−0.03 (−7.32 to 7.27)	0.995
Overall		–		**0.403**
Breast Density		68.3 (64.1–72.5)		
A	81			
NA	4		−5.06 (−24.28 to 14.16)	0.604
B	72		0.62 (−5.46 to 6.70)	0.840
C	35		4.35 (−3.24 to 11.94)	0.260
D	8		9.82 (−4.09 to 23.72)	0.165
Overall				**0.493**
Mammogram size (mm)	199	71.7 (66.9–76.5)	−0.12 (−0.37 to 0.12)	**0.315**
Ultrasound size (mm)	198	74.5 (69.4–79.5)	−0.36 (−0.67 to −0.05)	**0.022***
Neoadjuvant Therapy		69.8 (67.0–72.6)		
None	177			
Endocrine	9		3.51 (−9.30 to 16.33)	0.589
Chemo	14		−5.60 (−16.02 to 4.81)	0.290
Overall				**0.476**
Intra-operative data				
Surgeon		66.3 (60.8–71.9)		
Registrar with consultant scrubbed	46			
Registrar with consultant scrubbed	41		0.55 (−7.52 to 8.63)	0.893
Surgeon 1	37		6.64 (−1.65 to 14.9)	0.116
Other consultant	35		5.59 (−2.84 to 14.02)	0.193

Variable	*N*	Constant (95 % CI)	Coefficient (95 % CI)	*p*value
Surgeon 2	15		2.34 (−8.84 to 13.52)	0.680
Surgeon 3	15		3.94 (−7.24 to 15.12)	0.488
Surgeon 4	11		8.49 (−4.12 to 21.11)	0.186
Overall				**0.578**
Level of surgeon		71.9 (68.4–75.4)		
Consultant	113			
Trainee, supervisor unscrubbed	46		−5.56 (−12.09 to 0.95)	0.094*
Trainee supervisor scrubbed	41		−5.02 (−11.81 to 1.78)	0.147
Overall				**0.146**
Type of surgery		69.8 (67.0–72.6)		
WLE	181			
Other complex	19		−1.87 (−10.9 to 7.19)	**0.685**
Axillary surgery		79.5 (71.1–88.0)		
Nil	19			
SLNB or sampling	150		−9.80 (−18.76 to −0.84)	0.032
ALND	31		−16.71 (−27.44 to −6.00)	0.002
Overall				**0.010***
Re-excision of margins		70.3 (67.4–73.2)		
No	169			
Yes	31		−4.74 (−12.05 to −2.57)	**0.203**
Pathology				
Pathology size (mm)	200	72.5 (67.3–77.6)	−0.13 (−0.33 to −0.07)	**0.199**

Variable	*N*	Constant (95 % CI)	Coefficient (95 % CI)	*p*value
Weight of specimen (g)	200	73.0 (69.4–76.7)	−0.08 (−0.14 to −0.02)	**0.009***
Tumour type		69.0 (65.6–72.3)		
IDC + DCIS	126		0.00	
IDC	27		−1.35 (−9.29 to −6.60)	0.739
DCIS	16		8.34 (−1.61 to 18.28)	0.100
Other (including ILC)	31		0.80 (−6.71 to 8.31)	0.834
Overall				**0.384**
Nodal status		70.0 (66.9–73.2)		
Negative	137		0.00	
Positive	45		−5.26 (−11.58 to −1.06)	**0.102**
Adjuvant therapy				
Adjuvant chemotherapy		69.9 (67.0–72.9)		
No	161		0.00	
Yes	39		−1.75 (−8.45 to 4.95)	**0.608**
Endocrine Therapy		73.0 (66.1–79.8)		
No	30			
Yes	170		−3.98 (−11.40 to 3.44)	**0.291**
Timing to first radiotherapy fraction	200	68.3 (65.2–71.4)	−0.01 (−0.03 to −0.00)	**0.132**
Boost radiotherapy		69.9 (66.9–73.1)		
No	149			
Yes	51		−1.55 (−7.64 to 4.54)	**0.617**
Post-operative events				

Variable	*N*	Constant (95 % CI)	Coefficient (95 % CI)	*p*value
Infection		70.0 (67.2–72.9)		
No	171			
Yes	29		−3.18 (−10.7 to 4.35)	**0.405**
Seroma (breast and/or axillary)		69.8 (66.7–72.9)		
No	144			
Yes	56		−0.76 (−6.68 to 5.15)	**0.799**
Skin necrosis		–		–
No	199		–	
Yes	1			
Haematoma		69.7 (66.9–72.4)		
No	185			
Yes	15		−0.99 (−11.08 to 9.09)	**0.846**
Delayed Wound healing (>30 days)		70.4 (−67.8–73.1)		
No	192			
Yes	8		−20.4 (−33.6 to −7.2)	**0.003***
Time from surgery (years)	200	65.9 (60.0–71.8)	0.104 (−0.05 to 0.25)	**0.171**

The bold signifies the overall *p* value

*$p < 0.1$ therefore entered into a multivariate model in a forward stepwise manner with a 5 % significance level to identify any independent risk factors

Table 3
Multivariate linear regression analyses related to 'Satisfaction with breasts' from the BREAST-Q BCT module

Variable	Constant (95% CI)	Coefficient (95% CI)	P value
BMI at surgery	103.2 (87.5 – 118.9)	-0.76 (-1.23 - -0.29)	**0.002**
Delayed wound healing (>30 days)		-21.44 (-34.31 - -8.58)	**0.001**
Axillary surgery			
Nil			
SLNB or sampling		-12.02 (-21.08 - -2.96)	0.010
ALND		-18.81 (-29.52 - -8.11)	0.001
			0.003

Correlation between 'Satisfaction with breasts' and all other domains in the BREAST-Q BCT module

There was a statistically significant positive correlation between 'Satisfaction with breasts' and all of the other domains within the BREAST-Q BCT module (Table 4; Fig. 3). However, only 'Psychological wellbeing' and 'Sexual wellbeing' demonstrated a strong correlation; other domains demonstrated weak or very weak correlation.

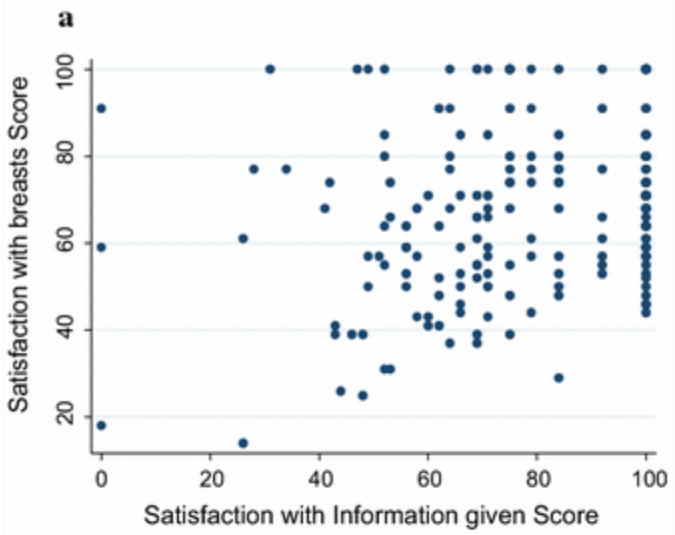
Table 4
Correlation between different domains of the BREAST-Q questionnaire

Domain 1	Domain 2	Correlation coefficient (Spearman's' rho)	Interpretation of correlation	Statistical significance (*p*value)
Satisfaction with breasts	Effect of radiotherapy	0.302	Weak	<0.001
Satisfaction with breasts	Psycho-social wellbeing	0.606	Strong	<0.001
Satisfaction with breasts	Sexual wellbeing	0.689	Strong	<0.001
Satisfaction with breasts	Physical wellbeing	0.354	Weak	<0.001
Satisfaction with breasts	Satisfaction with information	0.288	Weak	<0.001
Satisfaction with breasts	Satisfaction with breast surgeon	0.165	Very weak	0.021
Satisfaction	Satisfaction	0.184	Very weak	0.0009

Domain 1	Domain 2	Correlation coefficient (Spearman's' rho)	Interpretation of correlation	Statistical significance (*p*value)
with breasts	with medical team			
Satisfaction with breasts	Satisfaction with office staff	0.211	Weak	0.003

Spearman's correlation coefficient measures the strength of the monotonic relationship between paired data and may lie between −1 and 1. 0−0.19 = very weak, 0.2−0.39 = weak, 0.4−0.59 = moderate, 0.6−0.79 = strong, 0.8−1 very strong

$p < 0.05$ is considered a statistically significant correlation


a
Satisfaction with breasts Score
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20
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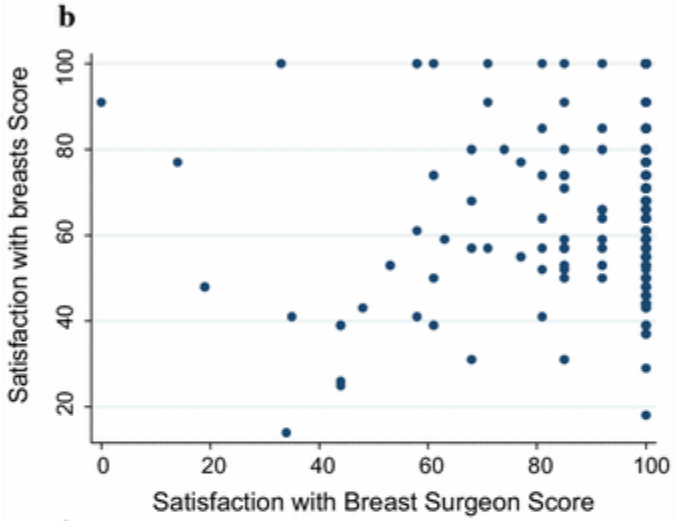
Satisfaction with Information given Score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Satisfaction with Breast Surgeon Score


c
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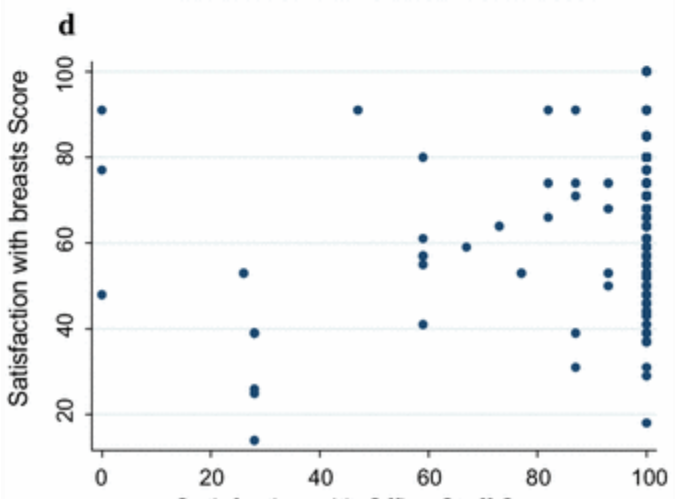
Satisfaction with Medical Team Score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Satisfaction with breasts Score
20
40
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100

Fig. 3

Correlation between ‘Satisfaction with breasts’ and the process of care domains. **a**Correlation between ‘Satisfaction with breasts’ and ‘Satisfaction with information given’. **b**Correlation between ‘Satisfaction with breasts’ and ‘Satisfaction with breast surgeon’. **c**Correlation between ‘Satisfaction with breasts’ and ‘Satisfaction with medical team’. **d**Correlation between ‘Satisfaction with breasts’ and ‘Satisfaction with office staff’

Discussion

This is the first study reporting complete BREAST-Q results in patients who have undergone breast conservation as opposed to mastectomy with or without reconstruction. Although Atisha et al. [5] evaluated satisfaction after BCT, the mean and median scores for each domain of the BREAST-Q BCT module were not reported. Currently, post-operative PROMs are not routinely used to measure levels of satisfaction and quality of life in women undergoing BCT, despite approximately 2.8 million women living in the USA with a current diagnosis or history of breast cancer [6]. In the UK, approximately 60 % [7] and in the USA 64.5 % [8] of women with breast cancer opt for breast conservation as their surgical treatment. The American Society of Plastic Surgeons [9], the UK's Association of Breast Surgery, the British Association of Plastic and Reconstructive and Aesthetic Surgeons and the Royal College of Surgeons of England [10] recognise the use of PROMs as an end-point in studies and a tool for quality control, and it is widely accepted that the aesthetic and functional outcomes after breast cancer surgery correlate with higher quality of life [11–13].

A mean score of 69 for 'Satisfaction with breasts' in our BCT patients is higher than that described in the UK National Mastectomy and Breast Reconstruction Audit (NMBRA) [10], where, eighteen months after surgery, scores were 56 for those undergoing mastectomy alone and 55, 64, 65 and 64 for immediate reconstruction with implant only, pedicle with implant, autologous pedicle flap and free flap, respectively [14]. It might be expected that the score for BCT would be higher than mastectomy with reconstruction since it is often a day-case procedure with preservation of skin sensation and the nipple in most cases. However, it can be argued that women who undergoing mastectomy and reconstruction undergo a longer programme of care which requires a higher level of patient involvement and decision-making. Patients who are involved in breast cancer decision-making have

improved long-term quality of life [15–17], which may also contribute to their satisfaction with the appearance of their breasts.

In our study, the lowest response rate was for 'Sexual wellbeing'. Only 62.5 % of participants completed that domain of the questionnaire. This also had the lowest mean score at 56. Other studies using the BREAST-Q in the reconstructive setting have also found this domain to have the lowest scores [14, 18, 19]. It is well known that women who have been treated for cancer may suffer with female sexual dysfunction (FSD) [20]. However, a recent prospective study in women one-year post-BCT found no significant difference in FSD compared with a healthy control group when using several validated questionnaires, though not the BREAST-Q [21]. BREAST-Q 'Sexual wellbeing' scores vary in the literature ranging from 39.5 [22] to 81.7 [23]. Further research into the scores for this domain in women who are not undergoing any form of breast surgery (oncological or cosmetic) is required to determine whether there is an unmet need in our patients or whether these results simply reflect the sexual wellbeing of women in the general population. The low response rates may be due to feelings of unease, cultural taboo or perceived irrelevance of the domain.

The BREAST-Q is validated and has been used in many studies, particularly in the setting of breast reconstruction [24]. Used over time, or in conjunction with the pre-operative baseline questionnaire, changes in an individuals' satisfaction and quality of life can be identified. It is also possible to compare two or more groups of women. The team that developed the BREAST-Q [25] has adopted the view of Norman et al. [26] that discrimination for changes, that is the minimally important difference, in health-related quality of life for chronic diseases appears to be approximately half a standard deviation. However, if the questionnaire is used as a one-off assessment, there is not yet a body of literature to suggest an acceptable mean or median score for a

surgeon or clinical unit to use a benchmark, or what may be considered a ‘satisfied’ or ‘less satisfied’ patient.

The current literature on risk factors for poor aesthetic outcome after BCT is variable in terms of design, size, timing and modality of assessment. The most common factors which have been reported to affect the aesthetic outcome include BMI [27], age [28–30], ethnic origin [29], menopausal status [29], tumour size [29, 31–35], whether the tumour is palpable [36], location of the tumour [28, 30, 35, 37, 38], surgical technique [31], specimen size/volume [29, 34,36–38], axillary surgery [31], incision/scar [27, 29, 38], re-excision [36], post-operative complications [37, 38], type of adjuvant radiotherapy [27, 29, 31, 32, 35–37, 39], chemotherapy [27, 29, 33, 35] and time since surgery [40].

Our multivariate analysis specifically looked at ‘Satisfaction with breasts’ to gain a patient perspective rather than an assessment by a panel of clinicians. It showed that high BMI, delayed wound healing and type of axillary surgery were significant risk factors for lower patient satisfaction score. The ‘cross-sectional’ study by Atisha et al. [5] also identified high BMI as an independent risk factor for lower satisfaction regardless of the procedure type. Others have identified high BMI as a risk factor for low satisfaction or adverse cosmetic outcome [41] after BCT. It is not possible to assign causation as to whether the high BMI truly leads to a worse appearance of the breasts after BCT or whether these patients have a poorer body image prior to breast cancer surgery which impacts on their evaluation of the post-treatment appearance. This highlights the importance of obtaining baseline data using the pre-operative module of the BREAST-Q to allow a patient’s pre-treatment opinion to be assessed and used as a reference point. Delayed wound healing is often associated with infection or dehiscence which may lead to a more prominent scar. Axillary surgery is a known risk factor for breast oedema [42–44] which may in turn lead to swelling, discolouration,

discomfort and a heavy sensation in the breasts. These factors may lead to dissatisfaction with the overall appearance of the breast.

Age was not a risk factor for lower satisfaction. We believe it is important that surgeons appreciate that appearance after surgery is valued by all patients regardless of their age. Our findings mirror a previous report that there is no correlation between age and breast satisfaction, psycho-social well-being nor satisfaction with the outcome in women undergoing post-mastectomy breast reconstruction [45]. Similarly, patients' satisfaction scores did not vary significantly according to time between surgery and answering the questionnaire. Our study included women between 1 and 6 years from surgery. It could be expected that satisfaction decreases as the contralateral breast changes naturally over time [46] and longer-term effects of radiotherapy occur [47–49]. Conversely, one might hypothesise that a patient may become more satisfied over time as they integrate back into 'normal' life after cancer treatment. Certainly, patients will have changes in satisfaction over the course of the breast reconstruction process and thereafter [50], however, in the case of BCT, a longitudinal study is required to investigate satisfaction over time to help understand this further.

There were significant positive correlations between 'Satisfaction with breasts' and all other domains of the BREAST-Q BCT module (Table 4). The strongest correlation was with 'psycho-social wellbeing' and 'sexual wellbeing', though any causative effect and its direction remains unclear. The correlation with 'effect of radiotherapy' and 'physical wellbeing' was weaker. Regarding the satisfaction with process of care domains (information, breast surgeon, medical team and office staff), the scatter graphs demonstrated that many women who gave high scores for the patient experience had a more varied 'Satisfaction with breasts'. This indicates that although some women have low satisfaction with their breasts after breast cancer treatment, they

were able to dissociate this with their satisfaction with the process of care (Fig. 3).

The strengths of this study include being the first publication of the full dataset for the BREAST-Q BCT module, reporting on a relatively large cohort of women. It could be used as a benchmark or comparator for other studies until larger national audits have taken place. The multivariate analysis gives insight into the factors that affect patient satisfaction and can help guide a surgeon in terms of managing expectations. The limitations are the single time point evaluation without pre-operative baseline data to understand longitudinal changes in patient satisfaction experience during the process of BCT and thereafter. Participation bias may be present as a result of the 14.2 % of the patients who declined to take part in the study and those who did not answer particular questions; nevertheless, the completion rate of 85.8 % of those who were contactable is favourable compared with other questionnaire-based studies in the literature.

Conclusion

Validated questionnaires provide clinicians with a useful insight into their patients' satisfaction. The BREAST-Q is becoming the gold standard and the data presented here may serve as a benchmark for future studies. High BMI, type of axillary surgery and delayed wound healing are risk factors for lower patient satisfaction. 'Satisfaction with breasts' is more strongly correlated with psycho-social and sexual wellbeing than physical wellbeing or effects or radiotherapy.

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Compliance with ethical standards

Conflicts of interest

There are no conflicts of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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