Breast Cancer: Targets and Therapy

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REVIEW

Systematic Review of Breast-Q: A Tool to Evaluate Post-Mastectomy Breast Reconstruction

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Purpose: The aim of this systematic review is to update and synthesize new evidence on BREAST-Q questionnaire's ability to reflect patient-reported outcomes in women who have undergone breast reconstruction surgery (BRS) following mastectomy.

Methods: PubMed, Science Direct, Google Scholar, Cochrane CENTRAL, and Clincaltrial.gov were searched for relevant studies from January 2009 to September 2021. Any interventional or observational studies that used BREAST-Q to assess patient-reported outcomes in the assessment of BRS following mastectomy were included.

Results: A total of 42 studies were eligible for inclusion in the review. Three were randomized controlled trials and 39 were observational studies. Compared with pre-operative scores, there was an improvement in all BREAST-Q outcome domains following BRS including 'satisfaction with breasts', "satisfaction with outcome" "psychosocial", "physical", and "sexual wellbeing". Sexual well-being had the lowest BREAST-Q score both pre-and post-operatively (37.8–80.0 and 39.0–78.0, respectively). Autologous BRS reports higher satisfaction and overall wellbeing compared to implant-based BRS. BREAST-Q has a higher and narrow internal consistency of 0.81 to 0.96 compared with other patient-reported outcome measures (PROMs; EORTC-QLQ, FACT-B, BR-23, BCTOS). The BREAST-Q questionnaire is the only PROM which allows patients to reflect on their care, surgical outcomes, and satisfaction collectively.

Conclusion: This review highlights the fact that BREAST-Q can effectively and reliably measure satisfaction and wellbeing of breast cancer patients after BRS. Comparatively, sexual wellbeing shows poorer outcomes following BRS and more longitudinal studies are necessary to understand the basis for these findings. Compared to other PROMs, BREAST-Q is reliable and specific to breast cancer surgery. Overall, BREAST-Q can help clinicians improve their quality of service, understand patient experiences, and may be used as an auditing tool for surgical outcomes.

Keywords: BREAST-Q, patient-reported outcomes, breast reconstruction surgery, mastectomy

Introduction

Breast cancer is the most prevalent type of cancer globally. In 2020 alone 2.3 million women were diagnosed with breast cancer worldwide, and 7.8 million women are currently living with it.[1] Over 30% of these women undergo a single mastectomy,[2,3] or prophylactic double mastectomy.[4] For many, the loss of one or both breasts is devastating, and breast reconstruction surgery (BRS) can improve outcomes for these patients.[5,6] Over 40% of women who undergo mastectomy opt for a BRS.[7]

Surgical management strategies for breast cancer may involve mastectomy, breast conservative surgery, BRS, and other reconstructive methods.[8–10] Age, body habitus,

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co-morbidities, previous surgeries, and other neo-adjuvant treatment influence the surgical method of choice.[11,12] Many of the women opting for BRS are often eligible for more than one type of breast reconstruction, therefore the timing of reconstruction, use of autologous tissue versus implants, short-versus long-term outcomes, and financial implications are all factors a patient may contemplate.[9]

Patient-reported outcomes (PROs) have become increasingly important in health care and assess the perception of health, quality of life (QoL), and functional status after treatment.[13] In cosmetic/reconstructive surgery, this is particularly important as the aim of the intervention is often to improve appearance, function, mental health, and QoL.[13] These tools can also help patients become informed, form realistic expectations, communicate with the surgical team, and gain greater satisfaction from the decision-making process.[14,15]

Patient-reported outcome measures (PROMs) are tools used to quantify PROs, often in the form of self-completed questionnaires.[16] The BREAST-Q is a PROM used to assess the unique outcomes of breast surgery patients.[17] Developed in 2009, BREAST-Q is made up of three procedure-specific modules: augmentation, reduction, and reconstruction.[18] The questionnaire examines outcomes commonly reported as important to women who have undergone a reconstructive procedure for breast cancer as well as health-related quality of life (HRQoL), psychosocial, physical, and sexual well-being, and satisfaction scales.[17] Since its development, BREAST-Q has been an effective measure for a spectrum of breast cancer surgeries.[19,20]

While several studies have used the BREAST-Q to assess the outcomes of patients undergoing breast surgeries for breast cancer, only one comprehensive systematic review exists on PROMs assessed by BREAST-Q which is now outdated and had heterogeneous results.[19] Hence, our review aims to update and synthesize new evidence on BREAST-Q's ability to reflect PROs in women who have undergone BRS following mastectomy. This review will address the following questions:

- To what extent has BREAST-Q evaluated PROM amongst patients who have undergone BRS?
- What were the outcome parameters used for BREAST-Q?
- How does BREAST-Q compare to other available PROMs?
- Is BREAST-Q an effective tool for measuring PROMs in BRS?

Methods

Search Strategy

This review adhered to the Preferred Reporting in Systematic Review & Meta-Analysis (PRISMA) guidelines and was listed retrospectively on the PROSPERO International Prospective Register of Systematic Review (CRD42021278102).[21] PubMed, Google Scholar, Science Direct, Cochrane CENTRAL, and trial registries (http://clinicialtrials.gov/) were searched for relevant studies published from January 1st, 2009 to September 30th, 2021. The search terms included: ("mastectomy" OR "breast removal surgery") AND ("breast reconstructive surgery" OR "BRS") AND ("BREAST-Q" OR "BREAST-Q questionnaire"). Furthermore, the references of selected articles were manually searched for relevant articles. After a screening of titles and abstracts, full-text reports were assessed for eligibility.

Study Selection and Outcomes

Inclusion criteria:

1. Primary research published in peer-reviewed journals including experimental such as randomized control trials (RCTs) and non-randomized trials, and observational such as cohort and case–control studies;
2. Studies with a target population included women with primary breast cancer who had mastectomy, or women who had prophylactic mastectomy. No restrictions were placed on age, type, and stage of breast cancer;
3. Studies reporting outcomes of any type of BRS following mastectomy;
4. Studies reporting outcomes using BREAST-Q.

Exclusion criteria:

1. Studies not published in English language:
2. Reviews, pre-prints, case reports, conference proceedings, conference abstracts, and letters or editorial opinions.
3. Studies on breast cancer in general without specific reference to BRS.
4. Studies that did not use BREAST-Q questionnaire as a PROM, or did not fully report BREAST-Q

satisfaction or health-related quality of life outcomes.

Data Collection and Extraction

Titles and abstracts of studies identified during the search were imported into Endnote X9 (https://endote.com) for preliminary screening. Full texts of potentially relevant papers were further screened using the eligibility criteria. These were done by two independent reviewers (IS and GB), and any disparity in either selecting eligible articles or assessing findings between the two reviewers was resolved through consultation with a third reviewer (NS). The following data were extracted from each included article into a pre-structured data collection sheet: year of publication, the country where the study was done, sample size, average age, the type of BRS, follow-up period, outcomes measured by BREAST-Q (such as reliability, and responsiveness), and average BREAST-Q scores.

Quality Assessment

The methodological quality of each study will be assessed using the Cochrane Systematic Review RCT risk of bias assessment tool 2 (RoB 2) for RCTs,[22,23] and Joanna Briggs Institute (JBI) Critical Appraisal Checklist for observational studies.[24] The RoB 2 tool addresses the following biases: random sequence generation, bias due to deviations from intended interventions, bias due to incomplete outcome data, bias in measurement of the outcome, and selective reporting. The items were assessed as "low risk", "high risk", or "some concerns". The JBI is a reliable and valid tool used to assess the methodological quality of observational cross-sectional studies. The checklist consists of eight questions, with 4 possible answers: 'yes', "no", "unclear", and "not applicable". A final question on whether to include, exclude, or seek further information on the study gives the overall judgement of the reviewer on that study. Disagreements were resolved through discussion with a third reviewer.

Data Synthesis

Data extracted from included articles were analyzed and combined in a narrative synthesis. Information from the studies were coded based on their methodologies and findings. These were then organized into subheadings and descriptive categories. Tables and charts were used to present the results. Through study screening, there was a wide variation of BRS types evident in literature, therefore a meta-analysis would show significant heterogeneity and ungeneralizable results.

Results

Study Characteristics

A total of 719 studies were identified from the literature search, and 43 met the eligibility criteria (Figure 1). All included studies identified their target population as patients who had a therapeutic or prophylactic mastectomy for breast cancer. The sample sizes ranged from 22 to 2048. Nineteen studies reported on implant-based BRS, 9 reported on autologous BRS, and 15 reported on both. One study did not include the type of procedure carried out on subjects. Most studies were conducted in the United States (13), with other countries being Italy (7), United States and Canada (4), Canada only (3), Netherlands (4), Germany (3), Mexico (1), Portugal (1), India (1), Australia (1), Denmark (1), United Kingdom (1) and Czech Republic (1). Studies were published between 2009 and 2021. Only three studies used a randomized controlled study design, while others used an observational design. Fifteen studies were of retrospective design while 28 were of prospective design. The average age ranged from 43.3 to 67 years, and the average follow-up duration at the time of administration of BREAST-Q tool ranged from 1 month to 6.5 years (Table 1).

Patient Reported Outcomes Using BREAST-Q

All studies used the breast reconstruction module of the BREAST-Q tool and aimed to assess the satisfaction and/or QoL of participants after BRS following mastectomy. All but one study reported the respondents' BREAST-Q scores on "satisfaction with breast" and "satisfaction with outcome" were reported by 31 studies. Wellbeing, psychosocial wellbeing, sexual wellbeing, and physical wellbeing (chest and upper body) were reported by 39, 39, and 37 studies, respectively. Thirteen studies assessed satisfaction with information, surgeon, medical team, and administrative staff domains, respectively.

On the BREAST-Q tool, the scoring for each domain ranges from 0, signifying the least possible level of satisfaction or wellbeing, to 100, signifying the highest. The average scores on satisfaction with breast domain ranged from 39.5 to 75.8 pre-operatively and 51.1–82.0 post-operatively while satisfaction with overall outcome ranged from 56.3 to 89. Average psychosocial well-being scores ranged from 54.3 to

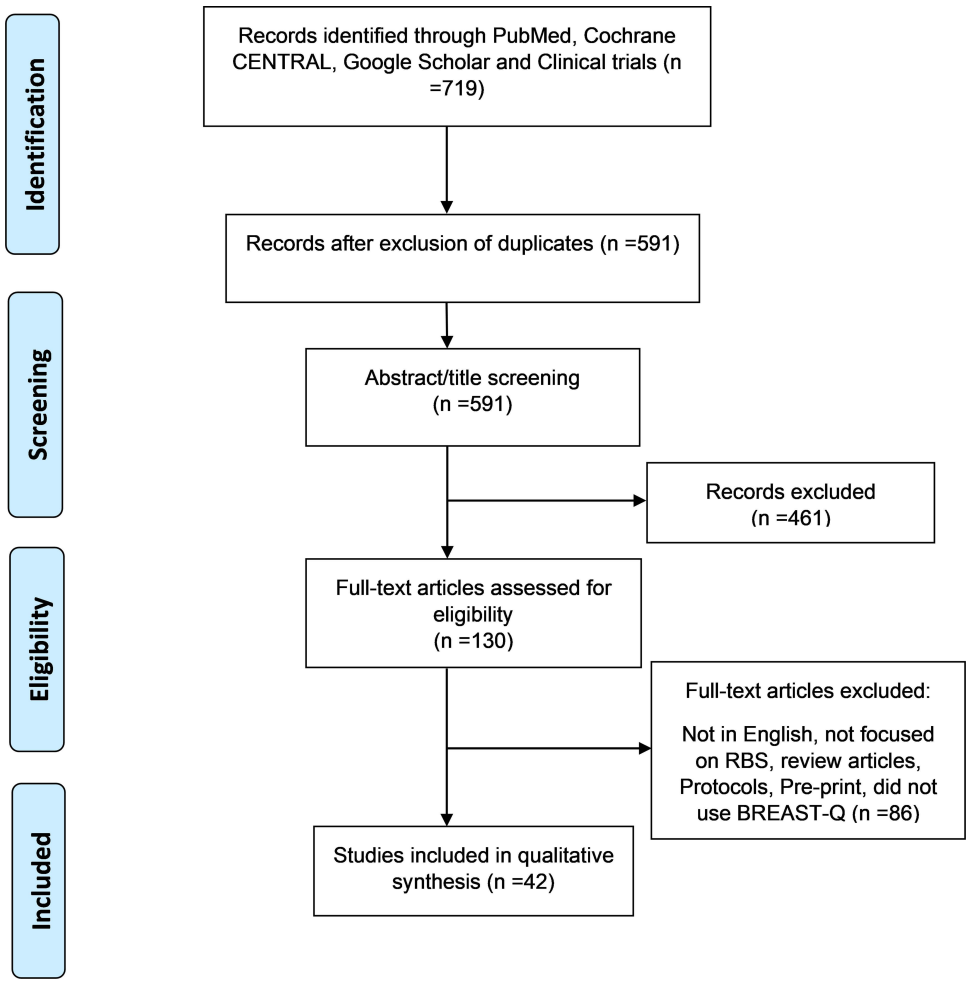

Figure 1 PRISMA flow diagram of selected studies.

77.9 on pre-operative assessment and 63.0–94.0 on post-operative assessment. Sexual well-being had the lowest average scores in all the studies, ranging from 37.8 to 80.0 on pre-operative assessment and 39.0–78.0 on post-operative assessment. Physical well-being (chest and upper body) had average scores ranging from 57.8 to 81.4 at baseline and 53.2–83.0 post-operatively. The studies also reported high satisfaction rates with medical care. Average scores for satisfaction with information ranged from 53.5 to 89, satisfaction with the surgeon, 83.2–100.0, Satisfaction with the medical team, 78.0–100.0, and satisfaction with the administrative team, 81.5–100.0.

BREAST-Q Response Rate

Of the 42 studies, only 15 reported the response rate for completion of the BREAST-Q questionnaire, which ranged from 38.4% to 98% (Figure 2).

Comparison Between Different BRS Types

Most studies compared PROs between different types of BRS. Comparisons were based on timing (immediate versus delayed),[25–27] type (implant-based versus autologous),[28–37] type of flap used (deep inferior epigastric perforators [DIEP], transverse rectus abdominis myocutaneous [TRAM], latissimus dorsi [LD] flaps),[38–40] type of Implant/tissue expanders used (acellular dermal matrices [ADM], silicone expanders, saline expanders),[41–44] placement of implant (pre-pectoral versus sub-pectoral),[45,46] number of stages (single stage versus multiple stages),[25–27,45] weight (normal weight, overweight, obese),[47] and age (less than 60 versus over 60, less than 65 versus over 65).[39,48]

Autologous vs Implant-Based BRS

In nearly all studies that compared PROs between autologous and implant-based BRS, autologous BRS had better

Table 1 Characteristics of Included Studies

S/N	First Author (Year)	Country	Study Type	Sample Size	Average Age (Years)[a]	Type of Breast Reconstruction
1.	Stein et al (2020)[41]	Canada	RCT	62	Alloderm group: 49 (12.2); Dermacell group: 54(9.6)	Direct-to-implant and two-staged pectoral BRS
2.	Casella et al (2019)[26]	Italy	Retrospective	397	46.5(13.6)	ADM and non-ADM tissue expanders
3.	Sorkin et al (2017)[42]	United States	Prospective	1297	48.4(10.4)	Autologous BRS
4.	Sinha et al (2016)[47]	Australia	Prospective	101	Normal weight: 46; overweight: 49; and obese patients: 49	IBBRS versus autologous. Fat grafting versus no fat grafting
5.	Bennett et al (2017)[28]	United States	Prospective	2048	49.4(10)	Autologous
6	Song et al (2016)[48]	United States, Canada	Retrospective	1809	Patients <65years: 49; patients >65years: 67	Autologous, IBBRS and mixed
7.	Davis et al (2014)[29]	United States	Retrospective	134	Median(range): 49(19–66)	Free TRAM flap (autologous) and IBBRS
8	Pirro et al (2017)[30]	Czech Republic	Prospective	65	TRAM group: 51.2; Implant group: 58.9	Autologous, IBBRS and Mixed
9.	Klifto et al (2020)[31]	United States	Retrospective	600	Control(normal): 43.3(15.2); BRS group: 49.9(9.4)	Direct-to-implant and Implant/tissue expander reconstruction
10.	Srinivasa et al (2017)[27]	United States	Prospective	1427	48.4(10.4)	IBBRS and autologous
11.	Santosa et al (2016)[32]	United States	Prospective	1531	NR	Pectoral Implant placement with TiLoop® bra-mesh
12.	Casella et al (2018)[43]	Italy	Prospective	179	56.3(23–79)	NR
13.	Ranieri et al (2021)[72]	Italy	Prospective	44	40.4(5.9)	Autologous: latissimus dorsi flap versus thoracodorsal artery perforator flap
14.	Rindom et al (2020)[38]	Denmark	RCT	40	NR	Autologous reconstruction versus IBBRS
15.	Reinders et al (2019)[33]	Netherlands	Retrospective and prospective	112	Autologous: 43(8.0); IBBRS: 49.4 (10.1)	Autologous versus IBBRS
16.	Albornoz et al (2014)[58]	United States, Canada	Prospective	633	Irradiated: 52.0(10.8); non-irradiated: 50.5(9.2)	IBBRS with versus without irradiation
17.	Koppiker et al (2018)[59]	India	Retrospective	78	NR	Autologous: DIEP versus TRAM flaps
18.	Ludolph et al (2015)[39]	Germany	Retrospective	179	Patients<60years: 48.2; patients>60years: 63.8	Autologous

(*Continued*)

Table 1 (Continued).

S/N	First Author (Year)	Country	Study Type	Sample Size	Average Age (Years)[a]	Type of Breast Reconstruction
19.	Allen et al (2020)[73]	United States	Prospective	405	50.1(7.9)	IBBRS versus autologous
20.	Santosa et al (2018)[34]	United States	Prospective	2013	IBRS: 48.1(10.5); Autologous: 51.6 (8.7)	IBBRS
21.	Koslow et al (2013)[74]	United States	Retrospective	294	No contralateral prophylactic mastectomy (CPM): 50.2; CPM:54.7	IBBRS and autologous
22.	Klement et al (2019)[35]	United States	Retrospective	96	Median (range) Implant: 49(27–74); Flap: immediate-51(26–68), delayed-50.5(32–71)	Autologous
23.	Menez et al (2017)[75]	Italy	Retrospective	98	51.7	Autologous: DIEP flap
24.	Razzano et al (2018)[76]	NR	Prospective	70	55(8.6)	Silicone implants and TiLoop® bra mesh
25.	Casella et al (2018)[43]	Italy	Prospective longitudinal	46	43.2(23–65)	Autologous: DIEP and TRAM flap
26.	Zhong et al (2011)[40]	Canada	Prospective	55	Median(range): 48(28–77)	IBBRS: saline and silicone implants
27.	Macadam et al (2010)[44]	Canada	Retrospective	143	Saline implant: 55.6(9.1); silicone: 52.3(9.5)	Autologous tissue and IBBRS
28.	Martinez-Lopez et al (2021)[36]	Mexico	Retrospective	153	56(14.2)	TRAM, Latissimus dorsi flap and IBBRS
29.	Brito et al (2020)[37]	Portugal	Prospective	284	48.8(9.0)	IBBRS-saline and silicone
30.	McCarthy et al (2010)[49]	Canada, United States	Prospective	520	Saline: 51.3(10.4); silicone: 53.7 (11.0)	TRAM flap, expander/implant,
31.	Hu et al (2009)[77]	United States	Retrospective	342	Median(range) Expander: 52.9(19–79); TRAM:52.3(34–72)	IBBRS and autologous
32.	Pusic et al (2017)[78]	United States, Canada	Prospective	1183	49.9(9.9)	IBBRS
33.	Negenborn et al (2018)[50]	Netherlands	Retrospective	208	43.2(10.1)	IBBRS with/without opposite breast reduction
34.	Shekhawat et al (2015)[79]	India	Prospective	147	Median(range): 48(29–72)	IBBRS alone and IBBRS with mesh

(*Continued*)

Table 1 (Continued).

S/N	First Author (Year)	Country	Study Type	Sample Size	Average Age (Years)[a]	Type of Breast Reconstruction
35.	Dieterich et al (2015)[80]	Germany	Retrospective	61	IBBRS alone: 52.8(9.4); IBBRS with mesh: 49.4(8.4)	Direct-to-implant, tissue expander/ implant
36.	Qureshi et al (2017)[25]	United States	Prospective	59	44(11)	Autologous, mesh
37.	Sewart et al (2020)[81]	United Kingdom	Prospective	891	Median(range) 50(45–58)	Autologous and IBBRS
38.	Eltahir et al (2014)[82]	Netherlands	Retrospective	92	Median(range) Autologous: 51 (35–78); Implant: 44.0(26.62)	DIEP flap
39.	Ochoa et al (2018)[83]	United States	Prospective	73	Median (range): 51(22–73)	IBBRS with pre-pectoral silicone implants
40.	Spindler et al (2021)[84]	Germany	Prospective	22	Median(range): 40.11(28–58)	Direct-to-implant
41.	Caputo et al (2020)[45]	Italy	Retrospective	94	Subpectoral-53; prepectoral:53	IBBRS with ADM and two-staged IBBRS
42	Negenborn et al (2018)[61]	Netherlands	RCT	142	IBBRS with ADM: 43.5(11.6) and Two-staged IBBRS: 47.4(12.2)	Direct-to-implant and two-stages pectoral BRS
43	Ghilli et al (2019)[46]	Italy	Prospective	132	48.88	Autologous: subpectoral prosthesis and ADM, pre-pectoral prosthesis and TiLoop® mesh

Notes: [a]Mean (standard deviation) except otherwise stated.
Abbreviations: ADM, acellular dermal matrices; BRS, breast reconstruction surgery; IBBRS, implant-based breast reconstruction surgery; NR, not reported; RCT, randomized controlled trial; TRAM, transverse rectus abdominis myocutaneous; DIEP, deep inferior epigastric perforators.

outcomes comparatively.[28–37] Table 2 shows the average BREAST-Q scores for the HRQoL subscales between autologous and implant-based BRS. In all domains, autologous BRS had higher post-operative scores compared to implant-based.

Type of Flaps and Implants Used

Only two studies in this review compared the PROs following autologous BRS with different flap types. Rindom et al compared the PROs between BRS with a latissimus dorsi (LD) flap and a thoracodorsal artery perforator flap, while Ludolph et al compared the PROs between DIEP and TRAM.[38,39] These two studies found no significant difference between the two groups in respect to all satisfaction and HRQoL domains, as both groups reported high satisfaction rates.[38,39] Similarly, two studies compared the use of saline and silicone implants. Both found that silicone implants showed better PROs compared to saline implants.[44,49] Sorkin et al found no difference between the use of ADM and non-ADM tissue expanders the PROs of patients.[42]

Single-Stage versus Multiple-Stage BRS

Negenborn et al and Qureshi et al found no significant differences in all BREAST-Q domains between patients who underwent one-stage BRS and those who underwent two-stages implant BRS using tissue expanders.[25,50] Another study found no significant difference in the PROs of patients in both direct-to-implant (DTI) group and tissue expander groups, except in sexual wellbeing, where the DTI group fared better.[27]

BREAST-Q versus Other PROMs

The BREAST-Q tool was compared with five other HRQoL PROM questionnaires (Table 3). BREAST-Q covers a wide range of domains compared with other PROMs and is the only tool that assesses individuals' satisfaction with care received. While all tools generally reported good

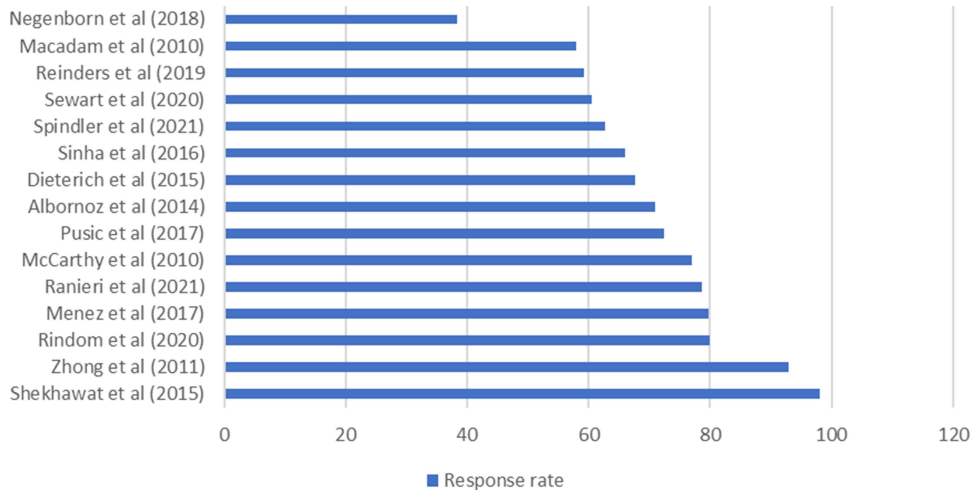

Figure 2 Response rate for completion of BREAST-Q questionnaire (%).

internal consistency/reliability with Rasch analysis, a statistical tool that assesses psychometric properties, BREAST-Q had a narrower range of reliability (0.81–0.96, compared to 0.69–0.9.0 and 0.46–0.91 as seen with EORTC QLQ 30 and BR-23 respectively) and is considered psychometrically robust.[17,51,52] The test re-test reproducibility of BREAST-Q ranges from 0.73 to 0.96.[17] Only the BREAST-Q reconstruction module is specific to HRQoL after BRS following mastectomy.

Methodological Quality of Studies

Of the included studies, only 3 were RCTs, and all had low risk of bias (Figure 3). The JBI Critical Appraisal Checklist was used to assess the methodological quality of the observational studies. All studies were of high quality and were therefore included in the review.

Discussion

The BREAST-Q questionnaire is a validated tool for evaluating PROs in patients undergoing BRS following mastectomy. Generally, BRS using either autologous or implant-based methods resulted in greater satisfaction and HRQoL. This review also found that autologous BRS had better PROs than implant-based BRS in all BREAST-Q domains. No statistical differences were noticed between the different types of flaps studied, however patients with silicone implants had better BREAST-Q scores indicating greater satisfaction and HRQoL. Patients that underwent one-staged and two-staged breast reconstructions fared similarly.

Alongside subjective outcomes, patient satisfaction is an indicator of surgical success and predicts psychosocial health following BRS. Within the included studies, average BREAST-Q scores for "satisfaction with breasts" domain ranged from 39.5 to 75.8 pre-operatively and increased to 51.1–82.0 post-operatively which can be attributed to a favorable change in body image. In contrast, satisfaction amongst patients who underwent mastectomy without BRS was poorer, with women being unhappy with their breasts and surgical scar despite the cancer being successfully treated.[53,54] Duggal et al found that over three-quarters of their participants opting for BRS had body image as their motivating factor.[55] These BREAST-Q scores and supporting findings suggest BRS should be indicated for patients who house concerns about body image, or hope to improve body image following mastectomy.

Table 2 Average BREAST-Q Score for Different Breast Reconstruction Surgeries Across Included Studies. Each Domain Ranges from 0, Signifying the Least Possible Level of Satisfaction or Wellbeing, to 100, Signifying the Highest (0–100 Range in Each Domain)

Type of Breast Reconstruction Surgery	Satisfaction with Breast	Satisfaction with Results	Psychosocial Well Being	Sexual Well Being	Physical Well-Being
Autologous	70.3	78.9	77.2	59.9	76.7
Implant-based	63.8	72.9	77.2	59.9	76.7

Table 3 Comparison of BREAST-Q Questionnaire with Other Patient-Reported Outcome Questionnaires

Patient-Reported Outcome Measures (PROMs) Questionnaires	Domains Assessed	PROMs Range	Psychometric Analysis (Reliability)	Specificity to Breast Cancer
BREAST-Q	9 domains: • physical well-being • psychosocial well-being • sexual well-being • satisfaction with breast • satisfaction with outcome • satisfaction with information • satisfaction with surgeon • satisfaction with medical team • satisfaction with admin staff	0–100 in each domain	(HRQoL after BRS) Internal consistency (Cronbach's alpha) ranges from 0.81 to 0.96;[17,51,52] Test re-test reproducibility 0.73 to 0.96[17]	Specific to BRS following mastectomy
EORTC-Q30	5 items on the functional scale: • physical, role, social, emotional, and cognitive functioning 9 items on the symptom scale: • pain, fatigue, financial impact, appetite loss, nausea/vomiting, diarrhea, constipation, sleep disturbance and quality of life	30 items: 0–100 in each domain	(HRQoL in cancer) Internal consistency (Cronbach's alpha) ranges from 0.69–0.9[85,86]	Not specific to breast cancer
EORTC QLQ BR-23	5 items on the functional scale: • physical, role, social, emotional, and cognitive functioning 4 items on the symptom scale: • systemic therapeutic side effect, breast symptoms, arm symptoms, upset by hair loss	23 items: 0–100 in each domain	(HRQoL after nreast cancer treatment) Internal consistency (Cronbach's alpha) ranges from 0.46–0.91[85,87,88]	Specific to breast cancer
Short-Form 36	8 domains: • physical functioning • physical role limitations • bodily pain • general health perceptions • energy/vitality • social functioning • emotional role limitations • mental health	36 items: 0–100 in each domain	(General HRQoL) Internal consistency (Cronbach's alpha) ranges from 0.72–0.91[89–91]	Not specific to cancer
FACT-B© David Cella, 1987, 1997	5 domains: • physical, social, emotional, functional well-being a breast-cancer subscale: • shortness of breath • self-consciousness about the way I dress • one or both of my arms are swollen or tender • I feel sexually attractive • I am bothered by hair loss • I worry that other members of my family might someday get the same illness I have • I worry about the effect of stress on my illness • I am bothered by a change in weight • I am able to feel like a woman • I have certain parts of my body where I experience pain	37 items	(HRQoL after breast cancer treatment) Internal consistency (Cronbach's alpha) ranges from 0.70–0.90[92–94]	Specific to breast cancer
BCTOS	3 domains: • functional status, cosmetic status, and breast-specific pain	22 items	(HRQoL after breast cancer treatment) Internal consistency (Cronbach's alpha) ranges from 0.81–0.91[95].	Specific to breast cancer

Abbreviations: BCTOS, breast cancer treatment outcome scale; BRS, breast reconstruction surgery; EORTC, European organization for research and treatment of cancer; FACT-B, functional assessment of cancer therapy – breast; HRQoL, health-related quality of life.

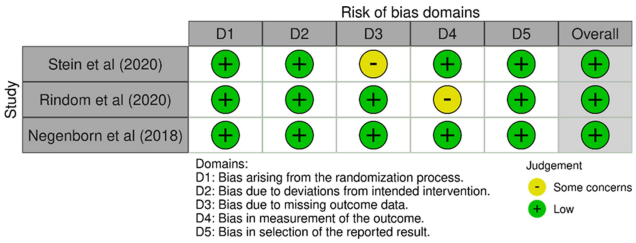

Figure 3 Risk of bias assessment for included RCTs.

The reviewed literature suggests BREAST-Q can indicate which BRS will yield greatest outcomes in satisfaction (Tables 1 and 2). All types of BRS yielded improvements with breast satisfaction following surgery and continued to improve over time except for Stein et al and Negenborn et al, who notably used ADM alongside tissue expanders/implant BRS.[41,50] In these surgeries, lower satisfaction with breast/s, overall outcome, physical and sexual wellbeing outcomes following BRS were observed.[41,50] A possible explanation for these findings is that ADM is associated with higher post-operative complications including seroma, infections, and red breast syndrome which may affect patient QoL and satisfaction.[41,50,56,57] Another factor that worsened BREAST-Q scores was radiotherapy, which is also associated with higher rates of complications in autologous and implant-based BRS.[33,58,59] Knowing the difference in complication rates in these BRS cohorts would better explain the low level of satisfaction observed.

Physical and psychosocial wellbeing following BRS was assessed in most of the included studies and showed overall improvement. An exception to this was Rowland et al who found patients undergoing mastectomy with and without reconstruction showed declined physical wellbeing, but this was equal when compared with women undergoing lumpectomy.[60] Another domain, sexual wellbeing, generally decreased following mastectomy compared with pre-operative BREAST-Q scores, and after BRS there was reportedly worsened to minimal improvements.[41,42,61] Overall, sexual wellbeing fared the least compared to all other domains which can be explained by the psychological effects of breast cancer surgery which can include anxiety, depression, and a feeling of loss of femininity.[62] Moreover, pain and discomfort in the months following surgery may impact the pursuit or desire for sexual activity. In the latter case, patient sexual well-being should improve following complete healing which could take up to a year or more.[63] Future longitudinal studies are needed to define the etiology of this domain because if decreased sexual wellbeing is due to mental health, this defines an opportunity to address it with a health professional.

The BREAST-Q questionnaire also allows patients to reflect on their relationship with the surgeon, the information that they received, and the care provided by the administrative staff.[17] Although most studies did not assess this domain, the ones that did show patients had high levels of satisfaction with the care that they received. More studies should focus on this PRO because these measures can be used to monitor and improve quality of care by surgeons and hospitals, and for auditing by health governance. Satisfaction with care has also been known to influence other outcome domains such as "satisfaction with breasts" and physical wellbeing including HRQoL. In future, this PRO should be focused upon more and be viewed as a potentially valuable tool for measuring quality of care.[64]

The BREAST-Q questionnaire was designed to measure outcomes which should be examined in BRS.[65,66] When examined by Rasch analysis, BREAST-Q has a high narrow internal consistency and test–retest reproducibility.[17,51,52] This strongly supports that it is valid and reliable tool for its purpose. Other PROMs used in assessing HRQoL in breast cancer patients are equally reliable but have wide reported range. In contrast to these questionnaires, BREAST-Q is also specific to BRS and is the only tool to accurately assess patient satisfaction with care (Table 3).[67,68] Chen et al reported BREAST-Q as one of the best tools for assessing HRQoL in breast cancer patients, stating that it was able to address surgery-specific issues, unlike other PROMs.[69] In support, the International Consortium for Health Outcomes Measurement endorsed BREAST-Q for breast cancer patients, highlighting its approval by healthcare governing bodies for assessing oncoplastic BRS outcomes.[70]

The current systematic review achieved its aims to examine the current evidence about BREAST-Q for management of post-mastectomy BRS and was able to compare it with the other PROMs (Table 3). Furthermore, the current study adopted a well-structured search strategy, followed the PRISMA guidelines and utilized manual searches to identify most eligible studies, and only included studies that were of good methodological quality. Despite these benefits, this study has several limitations. Firstly, the BREAST-Q tool collects self-reported data which can be unreliable; however, for subjective outcomes self-reported data are an accepted measure of choice.[71] Secondly, the level of heterogeneity in

BRS procedures prevented the performance of a meta-analysis and pooled analysis. Lastly, there was diversity amongst the geographic origin of included studies which may have introduced sociocultural factors. The impact of these would need to be statistically explored in meta-analysis, however the heterogeneity between studies made a meta-analysis unsuitable.

Conclusion

This review highlights that BREAST-Q can effectively and reliably measure satisfaction and HRQoL of breast cancer patients after BRS. Comparatively, sexual wellbeing shows poorer outcomes following BRS and more longitudinal studies are necessary to understand the basis for these findings. Overall, BREAST-Q can help clinicians improve their quality of service, understand patient experiences, and may be used as an auditing tool for surgical outcomes.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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