



Patient reported outcome measures (PROMs) following mastectomy with breast reconstruction or without reconstruction: a systematic review

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Abstract: The cornerstone of reconstructive surgery following mastectomy is to restore cosmesis and improve physical and psychological health. Consequently, it has become essential for instruments that measure surgical outcomes to include the direct perspective of patients. Many reviews have failed to show significant improvements in quality of life domains following breast reconstruction compared to mastectomy alone. However, with advances in surgical techniques and patient reported outcome measure (PROM) assessment tools designed precisely for breast reconstruction patients, a modern systematic review is warranted. An electronic literature review was performed using CINAHL, Cochrane Library and Medline (using PubMed) comparing patient reported outcome measures of patients undergoing *mastectomy alone* versus patients undergoing *mastectomy with breast reconstruction*. Studies in the English and Portuguese languages since the year 2000 were included. The review was undertaken adhering to PRISMA guidelines with last entry on the 31/5/2018. Full text review yield 42 articles of relevance to the inclusion criteria. The most widely used PROM instruments such as Breast-Q, EORTC-Q30/Q23, Short Form 36, FACT-B and others are explored. The specific difficulties conducting such studies and biases identified are investigated further. Studies comparing mastectomy alone against mastectomy with reconstruction show difficulties forming groups with similar clinical and epidemiological characteristics. There are inherent limitations to performing a randomised controlled trial on this topic, including matching patient groups in terms of age, socioeconomic background and cancer staging, and this affects the results of the PROM instruments. Within these limitations, the literature suggests that PROM support the use of breast reconstruction following mastectomy but care must be made selecting patients. The finding is supported by the National Institute for Health and Clinical Excellence (NICE) guidelines which state that breast reconstruction should be offered to all women undergoing breast cancer surgery.

Keywords: Breast cancer; patient reported outcome measures (PROM); breast reconstruction; mastectomy

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Introduction

Breast cancer is the second most common cause of cancer related death in females worldwide. It is estimated that over one million women are diagnosed globally each year with over 450,000 cancer related deaths (1). Mastectomy still has its consolidated role in breast surgery, although the refinement in screening and surgical techniques has led to the increase use of breast conserving surgery (2). Irrespective of the type of breast surgery chosen, a great proportion of women who undergo oncologic breast surgery perceive a negative self-image and experience negative changes in their sexuality and well-being following treatment (3).

The cornerstone of reconstructive surgery following mastectomy is to restore cosmesis and improve physical and psychological health. Because of such, it has become essential for instruments that measure surgical outcomes to include the direct perspective of the patient on reconstruction results. This change in standpoint to a patient centred approach has led to the development of patient reported outcome measures (PROM) specific to breast surgery, gaining significant popularity and validity over the past decade (4). Prior to the implementation of quality-of-life (QoL) evaluating tools, the majority of studies focused on surgical based outcomes such as morbidity and mortality. Moreover, only limited numbers of studies published prior to the year 2000 had direct patient input, with the majority designed for research and seldom included patient reports directly (5).

Previous reviews have failed to show favourable patient reported outcomes for breast reconstruction following mastectomy compared to patients undergoing mastectomy alone (6). This can likely be attributed to the relatively modern development of validated PROM tools used in breast reconstruction, which previous studies have lacked, and advances in surgical techniques. Given these limitations, the purpose of this systematic review is to evaluate the modern literature comparing PROMs of patients undergoing breast reconstruction following mastectomy compared to patient undergoing mastectomy as a single procedure.

Method

Search strategy

A systematic literature review was performed using the CINAHL, Cochrane Library and Medline (using PubMed)

adhering to the PRISMA statement (7). The keywords selected were: (patient reported outcome measures OR quality of life OR BREAST-Q OR satisfaction) AND (breast reconstruction OR implant OR DIEP OR TRAM OR latissimus dorsi) AND mastectomy. Articles were searched electronically by the main author with the latest entry added on the 31/5/2018. Reference lists of identified studies and previously published reviews were also explored.

Inclusion criteria

Only articles published in the English or Portuguese language from the year 2000 were included. Portuguese language was added to the review due to the first author being fluent in the language. Eligible articles included patients who underwent mastectomy recommended for invasive breast cancer or carcinoma *in situ*. Selected studies had to compare patients undergoing mastectomy alone against a cohort of patient undergoing mastectomy followed by breast reconstruction, thus, articles comparing different reconstruction options without a mastectomy alone control group were excluded. Studies were required to include patient reported outcome measures or any quality of life measure reported directly by patients. Articles only including mastectomy for prophylactic purposes were excluded with view that the holistic treatment for breast cancer has a direct influence on quality of life measures.

The process of identifying articles is summarised in *Figure 1* as a PRISMA statement diagram.

Results

The literature review yielded 52 articles for full text examination. Four were excluded due to being written in a language other than English or Portuguese (8-11) and 6 were excluded for not fitting other elements of the inclusion criteria (12-17). Thus, 42 studies comprised this appraisal, of which three were written in Portuguese (18-20). Twenty one articles were prospective in nature and 28 were published after the year 2010. The countries with the most publications were the USA and Brazil with 7 studies each closely followed by the UK with 4. Geographical differences in results are shown in *Table 1*. Totalling all articles, over 9,700 patients underwent mastectomy alone and 6,600 patients underwent breast reconstruction.

Sample size varied significantly when comparing studies, from the smallest with 21 patients (18) to the largest with 6,882 (2). Eleven articles used at least one of the

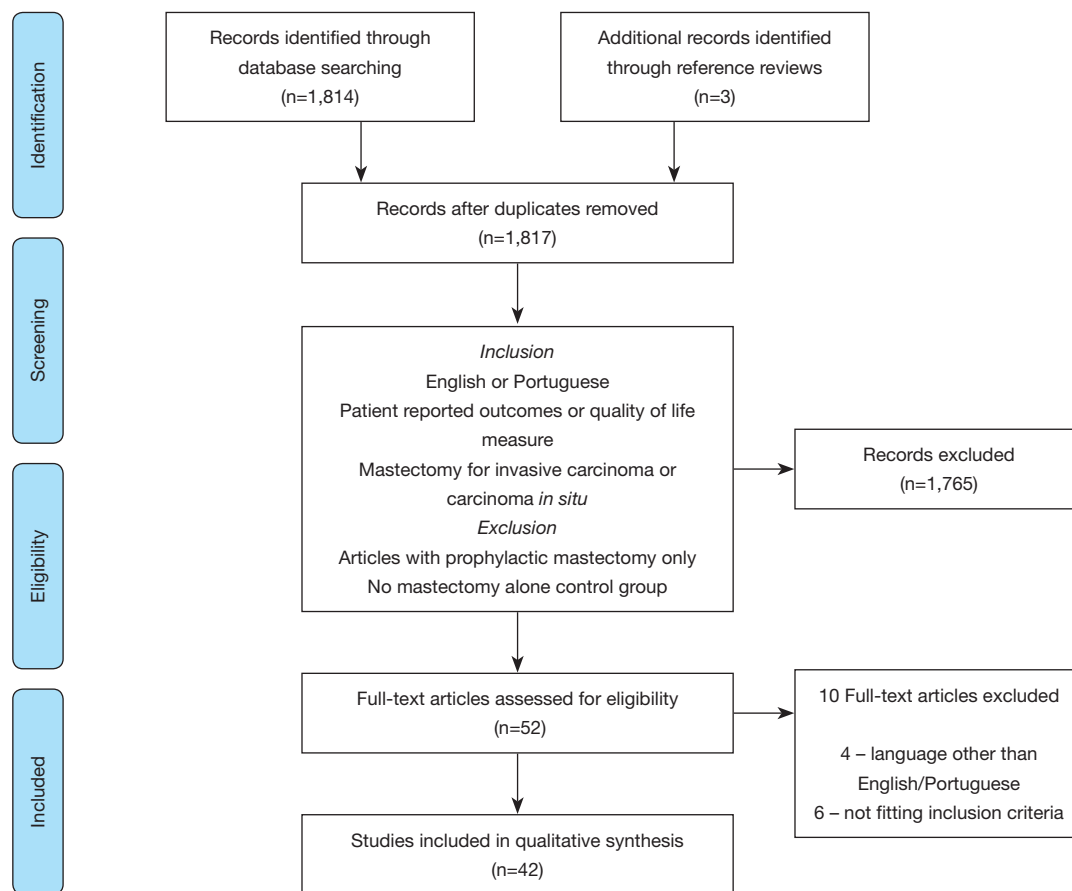


Figure 1 Graphical representation of the flow of citations reviewed in the course of this systematic Review adhering to PRISMA guidelines (7).

Table 1 Geographical variation in patient reported outcome measures and PROM tool used

Region	Number of articles	BR > MA (n articles)	BR = MA (n articles)	MA > BR (n articles)	Most common PROM tool (n of articles)
North America	11	7	3	1	Breast-Q (n=3)
Brazil	7	5	2	0	SF-36 (n=2)
Australasia	8	7	1	0	Breast-Q (n=3)
Europe	15	11	4	0	EORTCQ 30/Q23 (n=5)

>, superior in one of the arms; =, no statistical difference between arms. PROM, patient reported outcome measure; BR, breast reconstruction; MA, mastectomy alone.

Breast-Q modules as their prime PROM tool, followed by *EORTC-Q30/Q23* with ten studies, *Short Form 36* with seven studies and *FACT-B* with four studies. The remainder of articles used PROM tools including self-made questionnaires, psychiatric evaluations, self-esteem assessments and sexual well-being scales.

Patient reported outcome measure instruments

Breast-Q

The PROM *Breast-Q* (21) was designed in the mid to late 2000s with the aim to measure the quality of life and satisfaction among breast surgery patients undergoing

Table 2 Average breast-Q subscale scores with breast reconstruction (BR) and mastectomy alone (MA) in articles that chose breast-Q as the main PROM

Treatment type	Satisfaction with breast	Physical well-being	Sexual well-being	Psychosocial well-being	Satisfaction with care
BR	71	77	55	73	91
MA	49	76	44	65	92

PROM, patient reported outcome measure.

breast reconstruction. Breast-Q contains the following modules: *psychosocial well-being*, *physical well-being*, *sexual well-being*, *satisfaction with breasts* and *satisfaction with care*. Segments have further been developed for different surgery types including breast conservation, mastectomy and breast reconstruction, thus allowing for comparisons across divergent surgical groups.

Eleven articles have utilised Breast-Q as their primary outcome measure (2,22-31). Ten of these showed an improvement in Breast-Q score in patients where breast reconstruction was performed. Cancer staging was worst in the mastectomy arm in three studies, potentially confounding results (22,24,30). The single study that failed to show a difference between breast reconstruction compared to mastectomy alone utilised the single *psychosocial well-being* subscale of Breast-Q and breast implants was the reconstruction of choice (31). The average subscale scores of articles that utilised Breast-Q are displayed in *Table 2*.

EORTC-Q30/Q23

The European organization for research and treatment of cancer-Q30 (EORTC-Q30) is a general 30-item questionnaire for health-related quality of life assessment in cancer patients (32). EORTC-Q23 is a complementary breast cancer specific questionnaire that is generally used together with EORTC-Q30 and constitutes of 2 distinct scales (33). Body image, sexual functioning, future perspective and sexual enjoyment forms the *functional scale*, whereas domains of the *symptoms scale* include arm symptoms, breast symptoms, side effects of systematic therapy and hair loss (33,34). Despite been validated for the use in breast cancer surgery, both EORTC-Q30 and Q23 were not certified for use in breast reconstruction (35). The development of QLQ-BRR26, a breast reconstruction specific scale, aims to be used in conjunction to EORTC-Q30/Q23 and it is still undergoing phase 3 development (36).

Ten studies used EORTC-Q30/Q23 as their primary PROM instrument (20,37-45). Fallbjörk *et al.* used an ad

hoc questionnaire with inclusion of the EORTC-Q23 and was therefore included in this group (42). Three studies showed an improvement in QoL with breast reconstruction, 5 showed no difference between arms and 2 showed improvement in some PROM domains but not in global QoL. The majority of studies had age disparities between groups, the mastectomy alone cohort being significantly older.

Short form 36 (SF-36)

The SF-36 is a summarised version of 149 validated health-related questions first reported as part of a medical outcomes study of more than 22,000 subjects (46). It entails 36 items concerned with the assessment of QoL and contains eight domains: limitations in physical activities, limitations in social activities, limitations in role activities because of physical problems, limitations in role activities because of emotional problems, bodily pain, general mental health, vitality and general health perceptions (47). Despite its general usability, the SF-36 has not been validated for the use in breast cancer or breast reconstruction patients. In view of such, items such as body image, femininity and sexual well-being, may not be contemplated by the scales of the SF-36 (16). Furthermore, the scores can be distorted by comorbidities other than breast cancer that may affect patient is quality of life.

Seven articles used SF-36 as their primary patient reported outcome measure tool (18,48-52) and one article used both Breast-Q in conjunction with SF-36 (29). All articles showed that breast reconstruction patients had superior PROMs in at least one of the SF-36 domains when compared to mastectomy alone. In three studies, nearly all measures of SF-36 were better in breast reconstruction patients (18,48,51). Medina-Franco found statistically better reported outcomes only in younger females (49). The remaining 3 studies had significant changes only in some of the SF-36 domains and supplemented their methods with the addition of other PROM instruments—ultimately

showing an overall increase in patient reported quality of life domains (29,50,52).

FACT-B

A Functional Assessment of Cancer Therapy-Breast (FACT-B) quality of life questionnaire is a patient reported outcome tool utilised for the assessment of QoL after breast surgery. It has been previously validated on 295 breast cancer patients (53). The FACT-B questionnaire includes the domains of *physical well-being, social well-being, emotional well-being, functional well-being and doctor relationship*. Similar to the EORTC questionnaires, FACT-B has not been validated in the breast reconstruction population.

Four studies utilised FACT-B as their PROM of choice. Two studies found better physical wellbeing and body image in the breast reconstruction group, with other FACT-B measures not having a significant change (22,54). One particular study by Nissen and colleagues found that patients who underwent breast reconstruction scored significantly lower than those who underwent mastectomy alone in the domains of physical, emotional and functional well-being (55).

Other PROM tools

The remaining 14 studies used a myriad of other patient reported outcome tools. Three studies used sexual function scales, with all three finding better patient reported outcomes in the breast reconstruction group (56-58). Three studies used psychometric evaluation tools to assess mainly for anxiety and depression (59-61). Specific body image questionnaires were utilised in eight studies, with or without other PROM instruments used in combination (40,44,49,54,61-64). Examples of PROM instruments used included the *Body Image after Breast Cancer* (65), *Body Image Scale* (66) and the *Body Satisfaction Scale* (67). Three studies used their own questionnaire bases on other available tools (22,42,68).

PROM results

Eleven studies found that PROM were similar between patients that undertook breast reconstruction to that of patients who underwent mastectomy as a single procedure. Thirty studies had statistical significant improvement in the PROM with breast reconstruction, especially in the domains of body image, sexual well-being and breast satisfaction. Only a single study found worst quality of life

measures in the breast reconstruction arm (55). Articles included in this review and the PROM results comparing breast reconstruction with mastectomy alone can be found in *Table 3*.

Discussion

Undergoing breast reconstruction following mastectomy should optimally be an informed decision by the patient. Thus, all the articles included in this review are limited by the absence of randomisation. The result is an abundant dissimilarity between clinical and demographic characteristics between the breast reconstruction and mastectomy-alone groups, some of these are explored below.

Age difference

Matching the two study arms according to age proved to be a substantial challenge for most studies. Twenty-one studies reported statistically significant ($P < 0.05$) age difference between breast reconstruction and mastectomy groups, reconstruction patients tended to be younger. When translated into PROM results, six of these studies showed breast reconstruction to be equal or worst to mastectomy alone. Two studies subdivided their groups according to age and found contrasting results (48,49).

Efforts of comparison have limitations because of the disparities in age-related quality of life determinants. Generally, younger patients with breast cancer are more concerned with their physical appearance and femininity (19,71). In contrast, older breast surgery patients often view their breast appearance as a less important aspect of their quality of life and choose less involved operations to avoid complications (37). Complex reconstruction is paired with longer operative time, donor site morbidity and slower return to mobility, all of which could have detrimental effects on the elderly (55). Enewold *et al.* noted that the frequency of patient request for breast reconstruction significantly decreases with increasing age (72). Thus, given differences in age-related priorities, the implications of an older mastectomy-alone cohort would result in significant bias in patient reported outcomes. Similar can be said about a younger breast reconstruction group.

Socioeconomic differences

The impact of breast reconstruction in body image

Table 3 List of articles included in the systematic review. The methodology and type of PROM instrument used is included

Article	Method	PROM	Results	Level of evidence
Jeevan <i>et al.</i> (2)	Prospective	Breast-Q	BR > MA	III-2
Simeão <i>et al.</i> (18)	Prospective	SF-36	BR >> MA	III-2
de Oliveira <i>et al.</i> (19)	Prospective	WHOQOL-100	BR > MA	III-2
Martins <i>et al.</i> (20)	Retrospective	EORTC Q30/Q23 + DASH	BR = MA	III-2
Jagsi <i>et al.</i> (22)	Prospective	Self-made (Breast-Q/FACT-B)	BR >> MA	III-2
Razdan <i>et al.</i> (23)	Prospective	Breast-Q	BR >> MA	III-2
Barone <i>et al.</i> (24)	Retrospective	Breast-Q	BR >> MA	III-2
Atisha <i>et al.</i> (25)	Retrospective	Breast-Q	BR >> MA	III-2
Ng <i>et al.</i> (26)	Retrospective	Breast-Q	BR >> MA	III-2
McCarthy <i>et al.</i> (27)	Retrospective	Breast-Q	BR >> MA	III-2
Chao <i>et al.</i> (28)	Prospective	Breast-Q	BR >> MA	III-2
Eltahir <i>et al.</i> (29)	Retrospective	Breast-Q + SF-36	BR >> MA	III-2
Howes <i>et al.</i> (30)	Prospective	Breast-Q	BR > MA	III-2
Aguar <i>et al.</i> (31)	Retrospective	Breast-Q	BR = MA	III-2
Dauplat <i>et al.</i> (37)	Prospective	EORTCQ 30/Q23	BR >> MA	III-2
Sinaei <i>et al.</i> (38)	Retrospective	EORTCQ 30/Q23	BR >> MA	III-2
Penha <i>et al.</i> (39)	Prospective	EORTCQ 30/Q23 + Lymph-ICF	BR >> MA	III-2
Spatuzzi <i>et al.</i> (40)	Prospective	EORTCQ 30/Q23 + BIS	BR = MA	III-2
Cortés-Flores <i>et al.</i> (41)	Retrospective	EORTCQ 30/Q23	BR = MA	III-2
Fallbjörk <i>et al.</i> (42)	Prospective	Self-made (parts of EORTC-Q23)	BR = MA	III-3
De Gournay <i>et al.</i> (43)	Retrospective	EORTCQ 30/Q23 + MBROS S/Bi	BR > MA	III-3
Harcourt <i>et al.</i> (44)	Prospective	EORTCQ 30/Q23 + BIS + HADS	BR = MA	III-2
Shi <i>et al.</i> (45)	Prospective	EORTCQ 30/Q23	BR > MA	III-2
Hunsinger <i>et al.</i> (48)	Retrospective	SF-36	BR >> MA	III-2
Medina-Franco <i>et al.</i> (49)	Retrospective	SF-36 + BIS	BR > MA	III-2
Nicholson <i>et al.</i> (50)	Retrospective	SF-36 + HADS + visual scale	BR > MA	III-2
Veiga <i>et al.</i> (51)	Prospective	SF-36	BR >> MA	III-3
Zweifler <i>et al.</i> (52)	Retrospective	SF-36 + self-made questionnaire	BR > MA	III-2
Nano <i>et al.</i> (54)	Retrospective	FACT-B + BI + photo analysis	BR > MA	III-2
Nissen <i>et al.</i> (55)	Prospective	FACT-B + MUIS + POMS	MA > BR	III-2
Cortés-Flores <i>et al.</i> (56)	Retrospective	FSFI	BR >> MA	IV
Neto <i>et al.</i> (57)	Retrospective	FSFI	BR >> MA	III-2
Manganiello (58)	Prospective	Sexual Quotient-F	BR >> MA	III-3
Rubino <i>et al.</i> (59)	Prospective	Psych. interview	BR = MA	III-2
Al-Ghazal <i>et al.</i> (60)	Retrospective	Rosenberg self-esteem + HADS	BR >> MA	III-2
Noyan <i>et al.</i> (61)	Retrospective	Rosenberg self-esteem + BIS	BR > MA	III-2
Denewer <i>et al.</i> (62)	Prospective	BITS + BSS	BR = MA	III-2
Fung <i>et al.</i> (63)	Prospective	Chinese health questionnaire	BR = MA	III-2
Metcalfe <i>et al.</i> (64)	Prospective	Multiple	BR = MA	III-2
Markopoulos <i>et al.</i> (68)	Prospective	Self-made	BR >> MA	III-2
Fanakidou <i>et al.</i> (69)	Retrospective	Multiple	BR >> MA	III-2
Arora <i>et al.</i> (70)	Prospective	FACT-B	BR = MA	III-3

>>, superior in *most* aspects assessed in the PROM; >, superior in *some* aspects of the PROM; =, no statistical difference between arms. PROM, patient reported outcome measure; BR, breast reconstruction; MA, mastectomy alone. Level of evidence as per National Health and Medical Research Council (NHMRC) guidelines.

perception and quality of life is influenced by patient socioeconomic background and educational level (49). Fourteen studies had statistically significant disparities when comparing socioeconomic backgrounds. Patients undergoing breast reconstruction were more likely to be employed, live in urban centres, have higher income or have higher level of education when compared to patients undergoing mastectomy alone. The result would be a distortion in PROMs in support for breast reconstruction.

Studies from Turkey and Iran depicted the financial challenges of women who would like breast reconstruction but are unable to afford it (38,61). Having a lower education and socioeconomic background was also associated with poor pre-surgical decision making and increased risk of reporting low satisfaction (61).

Lymphoedema and adjuvant therapy

The majority of studies did not include their rate of lymphedema following the oncological procedures. Data can be extrapolated by taking into account the rates of stage 3 breast cancer and axillary lymph nodes resections although these were also poorly reported. Eight studies narrated the presence of significant disparities in cancer stage, lymphadenectomies or axillary clearance between groups. The majority reported worst staging within the mastectomy-alone arm. Breast cancer related lymphoedema has been shown to have a negative effect on the QoL of breast cancer survivors, possibly negating the positive effects of breast reconstruction (39).

Adjuvant therapies have been shown to negatively affect health-related quality of life (28). Seven articles reported disparities between rates of chemotherapy and radiotherapy. Four studies had higher rates of adjuvant treatment in the breast reconstruction arm (40,44,55,62). None of the 4 studies narrated superior PROMs with breast reconstruction, indicating that higher rates of adjuvant therapy may have negated the effects of the plastic surgery. In contrast, the remaining studies in which adjuvant therapies were more prominent in the mastectomy arms showed significant better outcomes with breast reconstruction (28,37,39).

Time since surgery and timing of reconstruction

With time, women tend to experience changes in the shape and outcomes of their breast reconstruction, and intuitively a changing nature of PROMs. Over time, women who

choose to undergo implant reconstruction experience decreased aesthetic satisfaction compared with autologous tissue reconstruction (2). As time passes, reduction in breast satisfaction is seen with all types of reconstruction options, with gluteal and thigh flaps having the worst long-term outlook (25). In contrast, patients who opt to undergo mastectomy alone show an overall increase in reported breast satisfaction over time. Timing of the reconstruction is also an important consideration. Only ten studies explored the impact of both immediate and delayed options and compared it to mastectomy-alone. Six of these showed no difference in PROMs, and 3 supported immediate breast reconstruction (IBR).

The long-term variations in quality of life measures in breast reconstruction are difficult to study because any health change may lead to shifts in health related QoL domains (73). Particular to breast cancer surgery, the first few months following an operation are usually accompanied by adjuvant therapies and surgical recovery. Measuring patient reported outcomes within this period produces lower PROM results. Similarly, studies trying to establish evidence of satisfactory restoration of quality of life after a long-intervals following breast surgery may encounter the confounding effects of other comorbidities. The use of specific PROM tools that target breast surgery and breast reconstruction is therefore recommended to minimise the confounding effects of other diseases.

Conclusions

The current study demonstrated that breast reconstruction following mastectomy has led to better patient reported outcomes compared to mastectomy-alone in the great majority of trials since the introduction of appropriate questionnaire instruments in the beginning of the year 2000. Care must be taken when interpreting the data as the lack of randomised controlled trial limits the control of population characteristics. Women of younger age, higher level of education and good pre-treatment health are more likely to seek breast reconstruction. We encourage the use of prospective trials due to the inability of retrospective studies to account for changes in pre-surgical and post-surgical quality of life as well as to minimise recall bias.

Quality of life embodies broader physical and psychological health, level of independence, social connections, the environment, and spiritual care. Variations can be justified by the influence of comorbidities, dealing with the diagnosis of breast

cancer itself and the adjuvant therapies involved in the treatment of the disease. In view of such, the use of validated quality of life questionnaires in breast surgery and breast reconstruction is paramount to minimise the bias of co-existing health issues. Recommendations for breast reconstruction should follow the National Institute for Health and Clinical Excellence (NICE) published guidelines on improving breast cancer outcomes and reconstruction should be available to all women with breast cancer at the initial surgical operation (74).

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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