Systematic Review on the Patient-Reported Outcomes of Tissue-Expander/Implant vs Autologous Abdominal Tissue Breast Reconstruction in Postmastectomy Breast Cancer Patients

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Given recent advances in the diagnosis and treatment of breast cancer, its mortality rates have fallen.[1] Consequently, issues relating to the quality of survivorship have become increasingly important. For most women, the threats, fears, and losses associated with the treatment of breast cancer not only concern their health and survival, but further include concerns about body image, sexuality, self-esteem, and social life. Focus in the management of breast cancer has therefore expanded to not only include survival but also restoration of a patient's quality of life after cancer.

In particular, mastectomy may lead to psychosocial problems such as anxiety, depression, poor body image, and impaired sexual function.[2,3] Evolving surgical techniques have encouraged recommendations proposing that the optimal management of mastectomy patients incorporates consideration of both oncologic principles and esthetic outcomes.[4] Breast reconstruction after mastectomy has become an available option for most women as a means to improve quality of life and well-being. The existing literature supports the notion that reconstruction is one of the most important determinants of long-term health, patient satisfaction, functional and psychosocial well-being in breast cancer patients, when compared with mastectomy-alone patients.[5,6] Consequently, breast reconstruction has evolved from simply being considered a cosmetic procedure toward becoming an integral aspect in the management and the long-term recovery of patients with breast cancer.

For patients and their health care providers, it is important to consider patient-reported outcomes (PROs) when navigating through the complex decision-making process in the management and treatment of breast cancer. Outcomes research provides patients and physicians with objective and reliable insight into the appropriateness and effectiveness of medical interventions to direct treatment decisions. As patients become more actively involved in directing their own health care, patient satisfaction offers a means to evaluate and compare options based on previous patients' views. Furthermore, in the existing reimbursement environment, patient satisfaction has increasingly been used as a quality indicator for policy formulation.[7-9]

Existing systematic reviews have so far focused on comparing PROs of patients receiving breast reconstruction after mastectomy to mastectomy alone.[10,11] In reality, on deciding to undergo reconstruction, patients and clinicians must consider a multitude of factors, such as the timing and the reconstruction technique. Making a well-informed decision often proves to be a daunting task even for experienced surgeons and highly educated patients. Studies exploring the issue of the timing of reconstructive surgery have begun to emerge,[12,13] although studies in the latter issue, comparing how PROs differ across approaches to reconstruction, are lacking. A systematic review of the existing literature would be optimal to assist in guiding the decision on selecting the approach to reconstruction that is based on the best available, comparative clinical evidence.[14]

Two major types of postmastectomy breast reconstruction procedures exist: prosthetic implant-based and autologous

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Abbreviations and Acronyms

AAT = autologous abdominal tissue
FACT-B = Functional Assessment of Cancer Therapy in Breast
MBROS = Michigan Breast Reconstruction Outcomes Study
OR = odds ratio
PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROs = patient-reported outcomes
SF-36 = Short Form 36
TE/I = tissue-expander/implant
TRAM = tranverse rectus abdominis myocutaneous

tissue-based reconstruction. Within each class, the most common approaches presently used are the 2-stage tissue-expander/implant (TE/I) and the autologous abdominal tissue (AAT) reconstruction techniques, respectively.[15] In an earlier systematic review, we explored the safety of these 2 approaches to reconstruction and found that, despite certain method-specific complications, TE/I reconstruction had a significantly higher risk of reconstructive failure and surgical site infection compared with AAT reconstruction, but lower rates of skin or flap necrosis.[16] In this study, we now explore how PROs differ over time between TE/I and AAT reconstruction in breast cancer patients after mastectomy. The AAT reconstruction techniques included any of the following: free-transverse rectus abdominis myocutaneous flap (free TRAM), muscle-sparing TRAM, deep inferior epigastric perforators flap (DIEP), superficial inferior epigastric artery flap (SIEA), pedicled-TRAM, or any variations of these.

METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline was followed throughout the design, implementation, analysis, and reporting of this systematic review and this review is registered with PROSPERO (CRD42012002942).

Search strategy

The process undertaken to identify published, peer-reviewed breast reconstruction studies is summarized in Figure 1. The following databases were searched: MEDLINE (1946—present; In-Process and Other Non-Indexed Citations); EMBASE (1996—present); Cochrane Library (Issue 4 of 12, April 2012); PubMed (for non-Medline records); and ProQuest Dissertations and Theses. Searches were restricted to the English language, with the search strategy based on controlled vocabulary terms such as the National Library of Medicine's Medical Subject Headings and relevant keywords (Table 1). Articles were restricted to those published from January 2000, with the latest search being conducted on August 26, 2013, to identify articles reflecting current clinical practice. This was particularly important given the continuous refinements to autologous tissue techniques and improvements in prosthetic technologies. References of relevant publications included after full-text screening were hand-searched for additional citations. If necessary, authors were contacted with a request to supply missing information.

Only studies examining PROs between TE/I and AAT reconstruction were eligible, meaning that studies that assessed reconstruction outcomes without a comparison group were excluded. The study population had to consist of women undergoing mastectomy for breast cancer (ie, studies with males or patients receiving prophylactic mastectomy were excluded). Research efforts that evaluated outcomes from a surgeon's perspective were not the focus in this study because a patient's perspective may differ significantly from a clinician's.[17] Papers had to measure outcomes that were patient-reported, including clinical and psychosocial outcomes, as either the main outcome or as a prominent feature of the overall study. Studies that reported unsolicited patient feedback were not included.

If any studies resulted in multiple publications, we reviewed both the primary and secondary papers as long as the focus of the PROs differed (eg, esthetic satisfaction, psychosocial satisfaction, pain). A sample size greater than 10 patients per study arm was necessary for inclusion because this would exclude case reports or case series. Studies in which data could not accurately be extracted were also excluded.

Titles and abstracts of the studies identified from the search strategy were independently screened for inclusion by 2 authors (BT, NZ) based on the predefined, previously mentioned criteria. The full text of each potentially eligible study was then independently reviewed by both reviewers. In cases of disagreement, decisions were reached by consensus.

Data extraction

A standardized data abstraction form was used to record the following information regarding each relevant study: study reference details (eg, first author, year of publication); description of setting; selection criteria; patient numbers; response rates; demographic and clinical characteristics of study participants; and outcome(s) of interest (ie, methods and results). The outcomes measures examined the following domains: patient satisfaction (eg, overall or esthetic satisfaction), quality of life, psychosocial or functional status, pain, and willingness to recommend breast reconstruction to others.

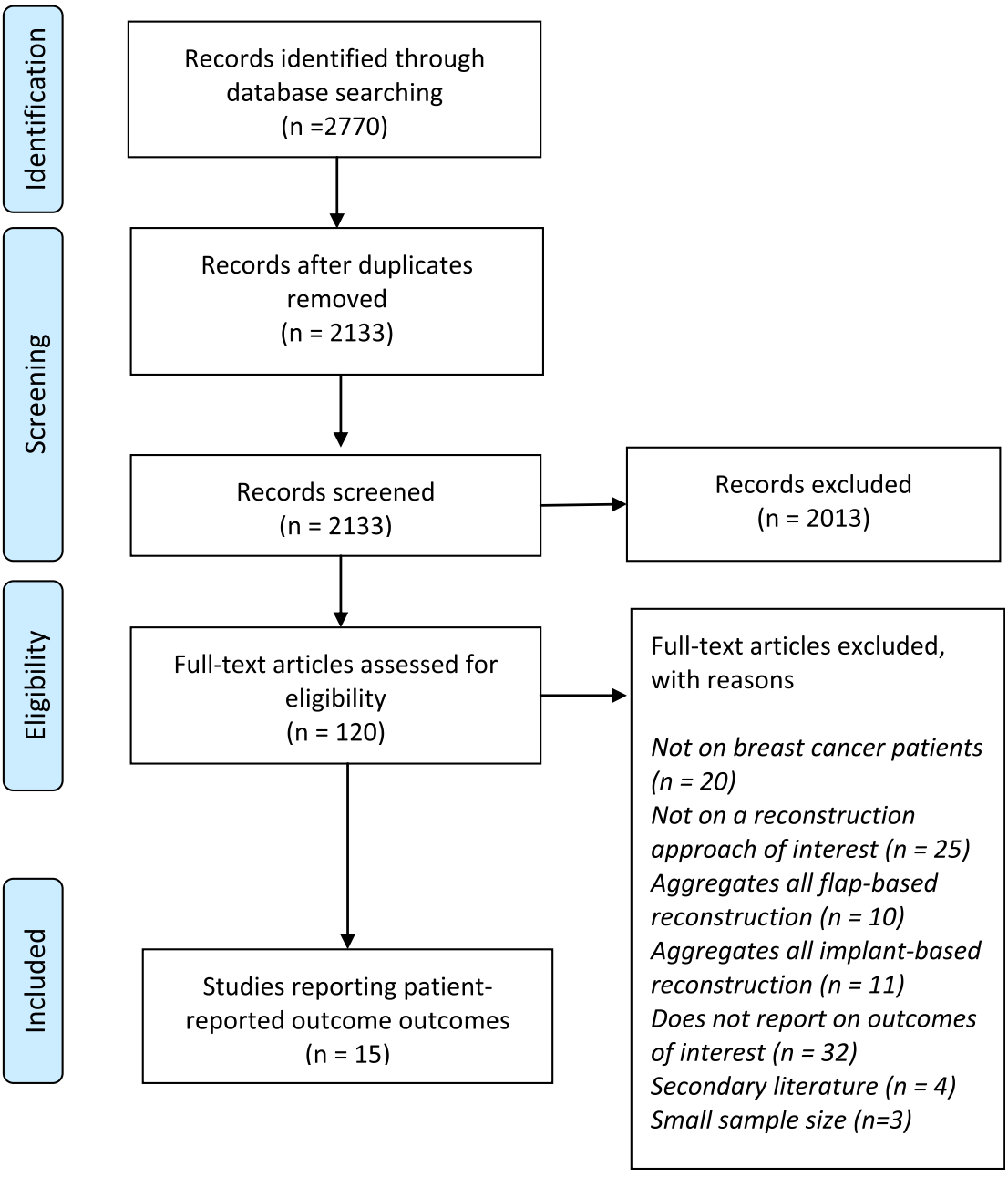

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram of literature search for articles on patient-reported outcomes of different approaches to breast reconstruction.

Data analysis

The methods for data synthesis were determined by the nature of the outcomes reported in the identified studies. The outcomes data were intended to be pooled and meta-analyzed using a random-effects model when heterogeneity was significant or otherwise, a fixed-effects model.

However, in view of the lack of randomized clinical trials and the heterogeneity in the PROs examined, the data precluded the use of any formal statistical techniques such as meta-analysis. Consequently, the main method of analysis was a narrative synthesis, with conclusions based on patterns observed across the included studies. These patterns were identified from the data abstraction tables.

The quality of each study was also assessed using the Newcastle-Ottawa scale.[18] All quality assessments were

Table 1. Search Strategy for MEDLINE

1.	Exp *Mastectomy/
2.	(mastectomy* or post-mastectom* or postmastectom* or mammectom*).ti,ab
3.	1 or 2
4.	exp *breast reconstruction/or exp *tissue expansion/
5.	(expander* or (tissue* adj expander*) or tissue-expander or tissue expansion device* or (breast adj3 reconstruct*)).ti,ab
6.	(mammoplast* or mammaplast*).ti,ab
7.	4 or 5 or 6
8.	exp *female/and exp *human/
9.	(female* or wom#n).ti,ab
10.	8 or 9
11.	3 and 7 and 10
12.	limit 11 to (human and English language and yr = "2000-Current")

The search strategy involves a combination of using key text words (rows 2, 5, 6, 9) that are present in the title and abstract along with keywords (ie, medical subject heading terms) that have been used in indexing an article (rows 1, 4, 8). The search is limited to humans only and of English language (row 12). ab, abstract; adj, adjacent; exp, explode; ti, title.

carried out independently by 2 reviewers (BT, NZ), with disagreements resolved by consensus.

RESULTS

The search retrieved 2,292 abstracts, of which 2,169 were excluded based on title/abstract screening. Of the remaining 123 publications, 15 observational studies met the selection criteria and were included following full-text review (Fig. 1). Agreement between the 2 reviewers ranged between moderate ($\kappa = 0.55$ [title/abstract screening]) and substantial ($\kappa = 0.73$ [full-text screening]). Studies that met our inclusion criteria are summarized in Table 2.

Description of the included studies

The 15 reports[7-9,19-30] represented 9 unique studies. Seven publications reported the primary findings of the Michigan Breast Reconstruction Outcomes Study (MBROS) or a subgroup analysis that explored either different PROs or time periods.[7,9,20-22,25,30] In total, the studies represented 1,393 patients: 893 patients received AAT reconstruction and 500 patients received TE/I reconstruction. All AAT reconstructions studied were either the free or pedicled TRAM flap procedure (Table 2). Most studies included both delayed and immediate reconstruction, with a single study including immediate reconstruction only.[27]

Most were cohort studies except for 1 cross-sectional study.[8] Of the 9 unique studies, the majority were conducted in North America[8,19,22,23,27,28] and 1 each from Italy,[26] Croatia/Austria,[24] and the UK.[29] One cross-national study involved patients from the United States, Canada, and Sweden[23] (Table 2).

In terms of the PROs, among the 15 publications, 8 articles reported esthetic satisfaction[7-9,19,20,24,28,29]; 7 each on general satisfaction[7,9,19,20,26,27,29] and psychosocial/functional outcomes[21-24,26,29,30]; 2 each on post-reconstruction pain,[23,25] and willingness to recommend reconstruction.[27,28] In terms of the methodologies used, all studies used simple survey instruments, with only a minority using a validated measurement tool.[8,21–23,26,30] Given the lack of consistent measurement methods and the varied follow-up duration, results from the individual studies could not be pooled. Instead, each study is presented narratively under the specific PRO and the results are further summarized in Table 3.

Esthetic and general satisfaction

Given that most studies explored both dimensions of esthetic and general satisfaction concurrently, their results are reported together. Several studies[7,9,19,20] measured both domains of satisfaction through a 7-item questionnaire developed for the MBROS. In the majority of the remaining studies, satisfaction was measured using nonvalidated questionnaires.[24,26-29]

Among studies suggesting similar satisfaction rates across different approaches to reconstruction, all had small sample sizes (<100 patients).[19,24,26,29] One such study explored individual elements of cosmesis (ie, reconstructed breast's shape with or without brassiere, contralateral match, mobility, definition/symmetry of inframammary fold, and consistency) and concluded that free-TRAM reconstructed breasts had significantly closer consistency ($p < 0.006$) and mobility ($p = 0.013$) to the natural breast compared with TE/I reconstructed breasts.[24]

In the remaining studies of larger sample sizes (>100 patients), a significant difference in esthetic and/or general satisfaction between the reconstructive procedures was found.[7-9,20,27] These studies tended to present an adjusted statistical analysis for which patient demographic and clinical characteristics were controlled.[7-9,20] Alderman and colleagues[9,20] demonstrated that recipients of AAT reconstruction tended to be esthetically and generally more satisfied than women receiving TE/I up to 2 years postreconstruction when adjusted for age, preoperative physical activity level, and timing of reconstruction. Although, the significant differences in general satisfaction by the method of reconstruction in the first year postreconstruction[9] converged by the second year,[20] AAT reconstruction continued to be associated with significantly greater esthetic satisfaction than TE/I reconstruction at both follow-up periods (years 1 and 2 postreconstruction).[20] Similar conclusions in esthetic satisfaction were observed in a cross-sectional study that grouped patients into

Table 2. Summary of Included Studies

First author, year	Country	Type of study	Mode of sampling	Intervention compared	Timing of reconstruction	Outcomes reporting			Study Quality	Funding reported
						Data accrual	Follow-up, mo	PRO Topics	Newcastle-Ottawa quality assessment score	
Adesiyun,[19] 2011	United States	Cohort	Retro	TE/I Pedicled TRAM Free TRAM	Delayed and immediate	Convenience sample	Median: 46.5 Range: 0.1 −114.8	General satisfaction Esthetic satisfaction	5	No
Alderman,[20] 2007	United States; Canada	Cohort	Prosp	TE/I Pedicled TRAM Free TRAM	Delayed and immediate	Convenience sample	0, 12, 24	General satisfaction Esthetic satisfaction	6	No
Alderman,[9] 2000	United States; Canada	Cohort	Prosp	TE/I Pedicled TRAM Free TRAM	Delayed and immediate	Convenience sample	0, 12	General satisfaction Esthetic satisfaction	5	Yes
Atisha, [21] 2008	United States; Canada	Cohort	Prosp	TE/I Pedicled TRAM Free TRAM	Delayed and immediate	Convenience sample	0, 12, 24	Psychosocial outcomes	5	No
Atisha, [7] 2008	United States; Canada	Cohort	Prosp	TE/I Pedicled or free TRAM	Delayed and immediate	Convenience sample	12	General satisfaction Esthetic satisfaction	4	No
Brockhurst,[22] 2008	United States; Canada	Cohort	Prosp	TE/I Pedicled TRAM Free TRAM	Delayed and immediate	Convenience sample	0, 24	Psychosocial outcomes	6	No
Hu,[8] 2009	United States	Cross-sectional	Prosp	TE/I TRAM	Delayed and immediate	Random sample	Subgroup: I) <5 years II) 6−8 years III)>8 years post-reconstruction	Esthetic satisfaction	5	Yes
Mullan,[23] 2007	United States; Canada	Cohort	Prosp	TE/I TRAM	Delayed and immediate	Convenience sample	0, 12	Psychosocial outcomes Pain	4	No
Roje,[24] 2010	Croatia; Austria	Cohort	Retro	TE/I Free TRAM		Convenience sample	0, 6	Esthetic satisfaction Psychosocial outcomes	4	No

(Continued)

Table 2. Continued

First author, year	Country	Type of study	Mode of sampling	Intervention compared	Timing of reconstruction	Outcomes reporting			Study Quality	Funding reported
						Data accrual	Follow-up, mo	PRO Topics	Newcastle-Ottawa quality assessment score	
Roth,[25] 2007	United States; Canada	Cohort	Prosp	TE/I TRAM	Delayed and immediate	Convenience sample	0, 24	Pain	6	Yes
Rubino,[26] 2007	Italy	Cohort	Prosp	TE/I Pedicled or free TRAM	Delayed and immediate	Consecutive sample	0, 12	General satisfaction Psychosocial outcomes	4	No
Saulis,[27] 2007	United States	Cohort	Prosp	TE/I TRAM	Immediate	Convenience sample	Range: 6–51	General satisfaction Willingness to recommend	4	Yes
Shaikh-Naidu,[28] 2004	United States	Cohort	Prosp	TE/I TRAM	Not specified	Convenience sample	Not specified	Esthetic satisfaction Willingness to recommend	4	No
Tzafetta,[29] 2001	United Kingdom	Cohort	Retro	TE/I Free TRAM	Not specified	Consecutive sample	Not specified	Esthetic satisfaction General satisfaction Psychosocial outcomes	4	No
Wilkins,[30] 2000	United States; Canada	Cohort	Prosp	TE/I Pedicled TRAM Free TRAM	Delayed and immediate	Convenience sample	0, 12	Psychosocial outcomes	6	Yes

TE/I, tissue-expander/implant; TRAM, tranverse rectus abdominis myocutaneous.

Table 3. Summary of Findings According to the Outcomes Domain

Outcomes	First author, Year	Direction of finding	Statistical adjustment	Outcomes measure used
Esthetic satisfaction	Adesiyun,[19] 2011	=	No	MBROS Questionnaire
	Alderman,[20] 2007	+	Yes	MBROS Questionnaire
	Alderman,[9] 2000	+	Yes	MBROS Questionnaire
	Atisha,[7] 2008	+	Yes	MBROS Questionnaire
	Hu,[8] 2009	+	Yes	BREAST-Q
	Roje,[24] 2010	+NS	No	Ad-hoc
	Shaikh-Naidu,[28] 2004	= (exception: + breast shape) Subgroup Analysis Bilateral: = Unilateral: + or +NS	Yes	Ad-hoc
	Tzafetta,[29] 2001	=	No	Ad-hoc
General satisfaction	Adesiyun,[19] 2011	=	No	MBROS Questionnaire
	Alderman,[20] 2007	=	Yes	MBROS Questionnaire
	Alderman,[9] 2000	+	Yes	MBROS Questionnaire
	Atisha,[7] 2008	+	Yes	MBROS Questionnaire
	Rubino,[26] 2007	+NS	No	Ad-hoc
	Saulis,[27] 2007	+	No	Ad-hoc
	Tzafetta,[29] 2001	=	No	Ad-hoc
Psychosocial or functional outcomes	Atisha,[21] 2008	Immediate reconstruction: = (exception: + social well-being) Delayed reconstruction: = (exception: + body image)	Yes	SF-36; FACT-B; Ad-hoc (for body image)
	Brockhurst,[22] 2008	=	Yes	SF-36; FACT-B; Ad-hoc (for activity of daily living)
	Mullan,[23] 2007	Not compared*	No	SF-36
	Roje,[24] 2010	=	No	Ad-hoc
	Rubino,[26] 2007	=	No	SASS; QL-index; HAM-A; HAM-D
	Tzafetta,[29] 2001	=	No	Ad-hoc
	Wilkins,[30] 2000	Immediate reconstruction: = Delayed reconstruction: = (exception: − vitality; − social well-being; + body image)	Yes	SF-36; FACT-B; Ad-hoc (for body image)
Pain	Mullan,[23] 2007	Not compared*	No	SF-36
	Roth,[25] 2007	= (exception: −abdominal pain; − abdominal tightness)	Yes	Ad-hoc
Willingness-to-recommend	Saulis,[27] 2007	=	No	Ad-hoc
	Shaikh-Naidu,[28] 2004	=	No	Ad-hoc

*Not compared as the reconstruction cohorts were drawn from different populations and the authors did not conduct any direct comparison between the cohort receiving autologous abdominal reconstruction and the one receiving tissue/expander implant.

+, Outcome for autologous abdominal tissue reconstruction better than tissue/expander implant reconstruction.

−, Outcome for autologous abdominal tissue reconstruction worse than tissue/expander implant reconstruction.

=, Outcomes equivalent, irrespective of reconstruction technique.

FACT-B, Functional Assessment of Cancer Therapy- Breast; HAM-A, Hamilton rating scale for anxiety; HAM-D, Hamilton rating scale for depression; MBROS, Michigan Breast Reconstruction Outcome Surgery; NS, statistically nonsignificant trend; QL-index, quality of life index; SASS, social adaptation self-evaluation scale; SF-36, Short-form 36.

3 postreconstructive time periods and adjusted the analysis for age, stage of cancer, receipt of radiotherapy, receipt of nipple reconstruction and receipt of symmetry procedure.[8] Esthetic satisfaction, measured with the BREAST-Q tool, found that although short-term (≤5 years) satisfaction was similar across both approaches to reconstruction, this diverged over time. Patients with AAT reconstruction had stable measures of esthetic satisfaction, which was not the case in the TE/I cohort. Indeed, patients who had undergone TE/I breast reconstruction more than 8 years earlier, compared with those who had undergone TE/I reconstruction less than 5 years ago, were significantly less satisfied with their breast appearance (adjusted odds ratio [OR] 0.10; 95% CI 0.02 to 0.48), softness (adjusted OR 0.14; 95% CI 0.03 to 0.64) and size (adjusted OR 0.13; 95% CI 0.03 to 0.62).[8]

Studies have further explored the determinants of satisfaction. In terms of esthetics, satisfaction did not vary across body mass index in recipients of AAT reconstruction but did affect the esthetic satisfaction of patients undergoing TE/I reconstruction: obese women tended to be less satisfied than women with normal weight when adjusted for age and timing of reconstruction.[7] Another study suggested the importance of laterality. Unilateral TRAM recipients rated several esthetic factors, including breast shape, symmetry of breast shape, and symmetry of breast volume significantly higher than unilateral TE/I recipients. However, no esthetic difference by reconstructive procedure was observed in patients undergoing bilateral reconstruction.[28] With respect to general satisfaction, one study suggested that a patient's body mass index is not a determinant when adjusted for age and timing of reconstruction.[7] Whether the development of complications is a determinant of general satisfaction remains speculative: one study supports this[26]; another contradicts it.[29] Among patients expressing dissatisfaction with their reconstruction, studies suggest that this may be associated with a diagnosis of moderate or high depression[26] and patients' dissatisfaction with inadequate preoperative counselling.[27]

Psychosocial and functional outcomes

Psychosocial and functional outcomes encompass a wide range of dimensions including physical/functional well-being, social functioning (including sexual life), and mental/emotional health (eg, anxiety, depression, body image). The majority of the studies used validated instruments, such as: Short Form-36 (SF-36),[21-23,30] Functional Assessment of Cancer Therapy in Breast (FACT-B),[21,22,30] social adaptation self-evaluation scale,[26] and quality of life index.[26]

In terms of physical and functional well-being, 2 unique studies reported this outcome.[22,23] Procedure type was found to have a limited effect on functional well-being in the MBROS study at both the first and second year postreconstruction, when the analysis was adjusted for age, preoperative scores on the psychosocial scale, and other demographic variables.[21,30] With respect to laterality, no procedural difference was observed in the 2-year postoperative scores for unilateral reconstruction. However, patients receiving bilateral free-TRAM reconstruction fared significantly worse than patients receiving pedicled-TRAM flap in the following subscales when adjusted for preoperative exercise level, timing of reconstruction, age, and presurgical score: SF-36's role limitations related to physical problems ($p = 0.004$); FACT-B's physical well-being ($p = 0.02$); and FACT-B's functional well-being ($p = 0.002$). The authors mention that caution must be taken in interpreting these results given the small sample size for bilateral reconstruction (ie, increased potential for type I error).[22] The other study reporting this outcome came to a different conclusion. Over a 1-year postoperative period, both reconstructive approaches led to a decline in physical functioning, although it was more significant in the TRAM group compared with the TE/I group.[23]

The majority of the studies suggest that measures of social life were significantly improved postreconstruction, irrespective of the approach,[21,23,24,29] although only 1 study controlled for age and preoperative score.[21] Studies so far have found no difference in social well-being according to procedure type.[26,30] However, an interaction between timing of reconstruction and method of reconstruction has been observed. Social well-being scores did not vary by procedure type among patients receiving immediate reconstruction, although in patients undergoing delayed reconstruction, recipients of TE/I reported significantly greater gains on the FACT-B social well-being subscale compared with women receiving TRAM reconstruction in the first postoperative year.[30] By the second year postreconstruction, patients receiving immediate reconstruction with pedicled-TRAM and TE/I had a decline in social well-being, while the free-TRAM patients' scores increased, when controlled for age and preoperative scores. This was considered a statistically significant procedural difference.[21] In delayed reconstruction, no procedure differences were observed because all approaches led to a decline in the social well-being scale by the second postoperative year.[21] Sexual life remained unchanged after reconstruction across the different methods of reconstruction.[24,29]

Both mental and emotional health were found to improve irrespective of the approach to breast reconstruction.[21,23] With respect to body image, recipients of TRAM had greater adjusted gains than TE/I patients at both the first and second year postreconstruction, which was found to be significant among patients receiving delayed breast reconstruction.[21,30]

Postreconstruction pain

Across reconstructive procedures, no difference existed in the adjusted general pain score at 1 year[23] and 2 years postreconstruction.[25] A multiple regression analysis was conducted to analyze the independent effects of procedure type and timing while controlling for baseline pain scores and ethnicity on pain. The TRAM patients were significantly more likely to report abdominal pain and tightness ($p < 0.0001$) than TE/I patients. The authors suggest that the evidence reflects ongoing problems with pain and musculoskeletal restriction even 2 years postreconstruction, which is suggestive of an association between the site of persistent pain and procedure type.[25]

Willingness to repeat and recommend reconstruction

Overall, patients' willingness to repeat the procedure and recommend it to a friend were similarly high for both approaches to reconstruction.[27,28]

Study quality and bias

Approximately half were small sample studies, involving fewer than 100 participants,[19,24,26,29] while the remainder had more than 100 participants[8,22,23,27,28] (Table 2). Even among the larger studies, none conducted a power calculation to ensure that the study was adequately powered to detect clinically meaningful differences, and attrition rates in most studies were high. Only 1 study had a follow-up rate exceeding 90%[30] and 1 had a follow-up rate greater than 80%.[29] The selection criteria for study participants were rarely random, with the exception of a single study[8] because convenience sampling was predominantly used. The majority of studies adjusted for potential confounders,[7-9,20-22,25,28,30] although it was not always clear which variables were controlled in the analysis.[7,8,21,28] Given the above methodologic shortcomings, the mean score on the Newcastle-Ottawa scale was 4.8 out of 9 (Table 2).

DISCUSSION

Firm conclusions on PROs between the approaches of reconstruction are limited due to methodologic weaknesses in the primary studies. Nonetheless, it appears that patients found breast reconstruction satisfactory, irrespective of the approach, and that breast reconstruction was a significant component in ensuring high-quality care for breast cancer survivors.

In the higher-quality observational studies identified within this systematic review, the results so far suggest that patient-reported satisfaction evolves over time. Recipients of AAT reconstruction tended to have higher esthetic and general satisfaction than TE/I patients.[9,20] However, general satisfaction levels off and converges over time between these 2 approaches, while the difference in esthetic satisfaction remains significantly higher over time as the measures remain stable for patients with AAT reconstruction, but declines for recipients of TE/I.[15] For the majority of psychosocial and functional outcomes, considerable uncertainty remains given a lack of studies and conflicting findings, although the results overall suggest that the method of reconstruction has a limited impact on these outcomes. Measures of general pain did not differ across methods of reconstruction,[23,25] although TRAM patients were found more likely to report abdominal pain and tightness than TE/I patients.[25] Despite differences in esthetic and general satisfaction across these procedures, the results suggest that patients were similarly willing to recommend the procedure or undergo it again.[27,28]

Previous investigators have demonstrated that autogenous tissue and implant-based techniques have different aging processes that may affect long-term satisfaction and esthetics.[20,21] The point at which outcomes stabilize remains unknown because long-term studies on PROs are lacking. In order to best address this, prospective studies should be designed with the aim to collect long-term data using validated and standardized scales.

Validated, procedure-specific scales such as the BREAST-Q[31] are beginning to emerge in breast surgery and measure patient-reported outcomes and satisfaction. Researchers conducting studies on this topic are encouraged to use these measurement instruments to assess PROs. If future studies were standardized and all included this tool, it would facilitate the use of meta-analytic techniques to pool the results across multiple studies and increase the statistical power when drawing conclusions regarding PROs.

It is also important that future studies collect and report patient demographics and clinical characteristics in their studies with completeness and transparency. This would then allow readers to make suitable judgements on the extent to which selection bias may exist. It would also support additional analysis to identify potential interaction effects between the method of reconstruction and other determinants of PROs.

Generalizability of studies

The generalizability of the published literature is limited due to methodologic weaknesses, such as the following:

1. Voluntary participation of the patients in all of these studies increases the risk of introducing volunteer bias because the outcomes between nonresponders and responders may differ, biasing the observed results. The use of convenience sampling could potentially introduce further selection bias.

2. Self-reported data may have introduced the risk of misclassification and misleading information.
3. Results from studies with a smaller sample size (<100 participants) may be less generalizable.
4. All studies were observational. As such, there is the potential for results to be influenced by confounders (eg, age, tumor stage, adjuvant therapy, laterality of reconstruction, timing of reconstruction, preoperative scores). In particular, previous systematic reviews[12,13] suggest that patients who had to live with a breast deformity and received delayed reconstruction were more likely satisfied with their reconstruction compared with their counterparts who never had to live with a deformity (ie, immediate reconstruction). Controlling for confounders is therefore important to support valid and unbiased conclusions. Two common methods observed were adjustment by regression or conduct of subgroup analysis. As stated previously, most studies conducted a degree of adjustment for potential confounders, although the number of variables adjusted was often limited.
5. The setting (predominantly North American and developed countries) and consequently, the patient demographics may differ in other jurisdictions, making extrapolation of these results to the rest of the world difficult.

Given the poor methodologic and reporting quality among studies, the results in this systematic review must be cautiously interpreted because issues regarding the generalizability of the results remain.

CONCLUSIONS

As highlighted in this systematic review, many knowledge gaps remain. There is some weak evidence that, with time, TE/I reconstruction becomes a less favorable approach in terms of patient satisfaction. Much work is still needed to ensure studies in this area are reported to the same standards as clinical data from other medical fields. For instance, research tools must be developed that are shown to be reliable and valid. This is particularly important, given the increase in bench-marking activities based on PROs. Furthermore, methodologic standardization will facilitate comparison across studies and support an evidence-based approach to assist clinicians and patients in making informed decisions about the appropriate approach to breast reconstruction.

Author Contributions

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Critical revision: Tsoi, Ziolkowski, Thoma, Campbell, O'Reilly, Goeree

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