

# The use of Patient Reported Outcome Measures in assessing patient outcomes when comparing autologous to alloplastic breast reconstruction: a systematic review

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Contributions: (I) Conception and design: All authors; (II) Administrative support: Peninsula Clinical School; (III) Provision of study materials or patients: R Phan; (IV) Collection and assembly of data: R Phan, WM Rozen; (V) Data analysis and interpretation: R Phan, WM Rozen; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Abstract: Breast reconstruction surgery after mastectomy has demonstrated positive psychological benefits, and is reflected in the number of patients undergoing the procedure, rising from 26.94% of patients after mastectomy in 2005, to 43.30% in 2014. Most of this is attributable to implant and expanderbased reconstruction, with the rate of free flaps only increasing from 1.25% to 3.96% in this time period. Increasingly, breast cancer patients have higher survival rates. There is now an emphasis on Value Based Health Care (VBHC), which focusses on outcomes, and that can be measured by Patient Reported Outcome Measures (PROMs). To date, there has been no systematic review to analyse PROMs between those undergoing autologous or alloplastic reconstruction, using validated measurement tools, to determine if there is a preferred technique from the patient's perspective. We performed a systematic search on EMBASE, and together with bibliographic linkage, identified 146 articles. After screening and assessment of articles through abstract, and full article appraisal, 13 were identified suitable for inclusion in this systematic review. Using BREAST-Q, satisfaction of breast and psychosocial well-being were rated highly by the autologous group when compared to implant-based reconstruction. Physical well-being was less significant, with the least significant difference noted for sexual well-being. EORTC-QLQ-BR23/C30 PROMs noted similar trends. SF-36 however, noted virtually no difference between the two methods of reconstruction regarding similar PROM quality of life (QoL) domains. From the patient perspective, autologous reconstruction is either equal to or superior to implant-based reconstruction, and should be offered to all patients.

**Keywords:** Patient Reported Outcome Measure (PROM); breast reconstruction; autologous; alloplastic; systematic review

Submitted Feb 20, 2019. Accepted for publication Jul 03, 2019. doi: 10.21037/gs.2019.07.04

View this article at: http://dx.doi.org/10.21037/gs.2019.07.04

## Introduction

Breast reconstruction surgery after mastectomy early on was demonstrated to have positive psychological benefits through improved cosmetic results and perceived body image (1-6), and is reflected in the number of patients undergoing the procedure, rising from 26.94% of patients after mastectomy in 2005, to 43.30% in 2014 (7). Most

of this is attributable to implant and expander-based reconstruction, with the rate of free flaps only increasing from 1.25% to 3.96% in this time period (7). As therapies such as targeted chemotherapy have improved, breast cancer patients have higher survival rates.

Although the literature reports improved long-term durability, reduced reconstructive failure and surgical

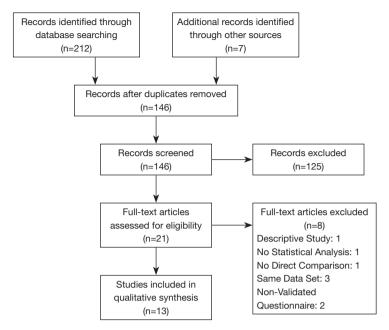


Figure 1 PRISMA attrition diagram.

site infection using autologous tissue (8), with shorter recovery period without donor-site morbidity for implantbased reconstruction (6,9), there has been a lack of focus on patient focused outcomes. There is now an emphasis on Value Based Health Care (VBHC), which focusses on outcomes, both short and long term, that are important to the patient, and can be measured by Patient Reported Outcome Measures (PROMs) (10,11). Defined as measurement of any of a patient's health status that comes directly from the patient, it has been incorporated as an independent parameter for health outcomes in conjunction with clinical outcome measurements (12,13). To date, there has been no systematic review to analyse PROMs between those undergoing autologous or alloplastic reconstruction, using validated measurement tools, to determine if there is a preferred technique from the patient's perspective.

## **Materials and methods**

This manuscript analyses the current literature on PROMs with regards to autologous and alloplastic breast reconstruction in accordance with PRISMA guidelines (*Figure 1*). We performed a systematic search on EMBASE from 1947 until January 2019 to identify all English literature using keywords: "patient reported outcome" and

"autologous"/"alloplastic" and "breast", "patient reported outcome" and "implant"/"expander" and "breast". We also identified relevant articles through bibliographic linkage. Two reviewers inspected the title and abstract of each citation to identify manuscripts suitable for review, with concordant papers included for review. Abstracts for conferences, letters to the editor and review articles were excluded from review.

Cohort studies reporting PROMs in female mastectomy patients undergoing autologous or alloplastic reconstruction using validated assessment tools were considered eligible. Case report and case series where statistical analysis was not performed were excluded from further consideration.

In total, 146 articles were screened after removal of duplicates. Following article appraisal, 13 articles were included in the systematic review (Figure 1). Excluded articles included those that did not use a validated questionnaire that would make objective comparison between studies difficult, did not provide numerical values or statistical analysis between the autologous and implant groups, or were studies based on the same data set, analyzed prospectively. Of the studies based on the same data set being analyzed prospectively, the article analyzing data across the entire study period was chosen.

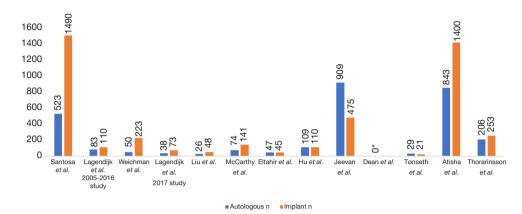


Figure 2 Number of patients recruited in each study, between the comparison groups. \*, denotes study which did not provide number of patients recruited.

Table 1 Baseline characteristics of the studies utilized in the systematic review

Paper	Charles to me	Publish year	n		Age (Avg)			BMI		
	Study type		Autologous	Implant	Autologous	Implant	P	Autologous	Implant	Р
Santosa et al. (14)	Prospective	2018	523	1,490	51.6	48.1	<0.001	29	25.4	<0.001
Lagendijk <i>et al.</i> , 2005–2016 study (15)	Cross-sectional	2018	83	110	45	42.5	<0.001	-	-	-
Weichman et al. (16)	Cross-sectional	2015	50	223	47.3	47.6	0.84	21.2	20.3	0.0001
Lagendijk et al., 2017 study (10)	Cross-sectional	2018	38	73	55		-	-	-	-
Liu et al. (9)	Cross-sectional	2014	26	48	49.1		-	25.4	ļ	-
McCarthy et al. (17)	Cross-sectional	2014	74	141	52	50	0.000	30.2	23.92	<0.0002
Eltahir et al. (18)	Prospective	2015	47	45	51	44	0.001	26	23	0.015
Hu et al. (19)	Cross-sectional	2009	109	110	52.3	52.9	0.76	-	_	-
Jeevan et al. (20)	Prospective	2017	909	475	*		-	*		-
Dean et al. (21)	Prospective	2016	147	•	-	-	-	-	_	-
Tønseth et al. (22)	Cross-sectional	2008	29	21	51.4	52.3	0.62	25.6	24.2	0.18
Atisha et al. (11)	Cross-sectional	2015	843	1,400	57.9	)	-	26.7	,	-
Thorarinsson et al. (23	3)Cross-sectional	2017	206	253	58		0.001	24.8	3	0.368

<sup>\*,</sup> median, not average specified by authors. P values in italic indicate statistical significance.

## **Results**

## Demographics of included studies

In total, 13 articles were included in the systematic review (Figure 1). Of the studies that discriminated patients been autologous and alloplastic reconstruction, a larger proportion of patients in the studies included underwent

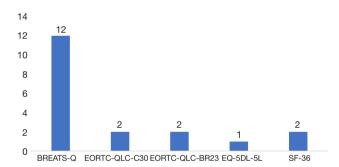
alloplastic reconstruction (n=4,389) when compared to those undergoing autologous reconstruction (n=2,937) (Figure 2).

There was a preponderance for patients undergoing autologous reconstruction in the respective studies to be older than those who had implant-based reconstruction, and this was often statistically significant (*Tables 1,2*). This

Table 2 Baseline clinical characteristics of the studies utilized in the systematic review

Paper	Unilateral			Bilateral			Prophylactic			Therapeutic		
	Autologous	Implant	Р	Autologous	Implant	P	Autologous	Implant	Р	Autologous	Implant	Р
Santosa et al. (14)	313	559	<0.001	210	931	<0.001	56	173	0.58	467	1,317	0.58
Lagendijk <i>et al.</i> , 2005–2016 study (15)	40	51	-	43	59	-	_	-	-	-	-	-
Weichman et al. (16)	98	19	0.53	125	31	0.53	120	40	0.02	228	41	0.02
Lagendijk <i>et al.</i> , 2017 study (10)	-	-	-	-	-	-	-	-	-	38	73	-
Liu et al. (9)	-	_	-	-	-	-	8		-	66		_
McCarthy et al. (17)	56	71	0.405	15	66	0.405		-	-	74	141	-
Eltahir et al. (18)	33	16	0.001	14	29	0.001	-					
Hu et al. (19)	71	60	0.07	29	40	0.07	-	-	-	-	-	-
Jeevan et al. (20)	-	-	-	-	-	-	-	-	-	-	-	-
Dean et al. (21)	-	-	-	-	-	-	-	-	-	-	-	-
Tønseth et al. (22)	-	-	-	-	-	-	-	-	-	-	-	-
Atisha et al. (11)	-	-	-	-	-	-	-	-	-	-	-	-
Thorarinsson et al. (23)	-	-	-	-	-	-	_	-	-	-	-	-

P values in italic indicate statistical significance.



**Figure 3** Distribution of validated PROMs utilized by the studies analyzed. Note: an article may use more than one PROM. PROM, Patient Reported Outcome Measure.

trend continued into studies that analyzed BMI, with those undergoing autologous reconstruction often having statistically significant higher BMI than those undergoing implant-based reconstruction.

Most studies did not differentiate between type of autologous reconstruction performed in their analysis, with only two papers analyzing reported PROMs between latissimus dorsi (LD), pedicle and/or free transverse rectus abdominis muscle (TRAM) flap and deep inferior epigastric perforator (DIEP) flap (20,23). One study focused exclusively on autologous TRAM flap reconstruction (19), and one on DIEP flap reconstruction (22). For studies using validated PROMs used to gauge mastectomy patients, a significant proportion utilized the BREAST-Q study (*Figure 3*).

## **PROMs**

#### **BREAST-Q**

# Satisfaction with breast

All studies utilizing BREAST-Q reported statistically significant increases in 'satisfaction with breast' with autologous when compared to implant reconstruction. Even after mixed-effects regression analysis by Santosa et al. (24), the increase was still statistically significant. Hu et al. (19) reported that TRAM reconstruction was preferred over implant in this regard. Jeevan et al. (20) noted statistically significant increases with those undergoing immediate LD, pedicled and free TRAM, DIEP and SIEA flaps when compared to implant-based reconstruction. This was apparent in both those that underwent immediate and

Table 3 Breast-Q domains and scores

OL - I	Satisfa	ction wit	h breast	Psychoso	ocial well-	-being	Physic	cal well-b	eing	Sexual well-being		
Study	Autologous	Implant	Р	Autologou	s Implant	Р	Autologous	s Implant	Р	Autologous	Implant	Р
Santosa et al., mixed effects regression model	7.94	_	<0.001	3.27	-	<0.05	1.69	-	<0.05	1.69	-	<0.05
Lagendijk et al., 2005– 2016 study	70.5	61.2	0.003	75.7	74.1	0.001	78.3	76.8	0.002	62.4	59.3	0.07
Weichman et al.	73.8	63.7	0.005	82.3	74.2	0.05	83.6	78.8	0.2	63.8	56.7	0.15
Lagendijk et al., 2017 study	71.9	53.8	<0.001	72.7	63.5	0.001	68.1	64.4	<0.001	60.2	52.6	0.046
Liu et al.	80.4	64.2	0	86.1	75.5	0.014	79.1	78.7	0.906	64.8	52.1	0.009
McCarthy et al.	. –	-	-	-	-	-	82.5	76.5	<0.0001	-	-	-
Eltahir et al.	75.19	65.51	0.023	73.96	77.18	>0.05	77.13	71.89	>0.05	60.89	61.14	>0.05
Hu et al., TRAM vs. implant	-	-	At 6–8 years, TRAM preferred over implant, P=0.01	-	-	-	-	-	-	-	-	-
Dean et al.	66.93	61.68	0.008	73.52	68.11	0.026	77.25	74	0.062	57.2	51.96	0.065

P values in italic indicate statistical significance. TRAM, transverse rectus abdominis muscle.

delayed reconstruction. Atisha *et al.* (11) noted through regression analysis that abdominal and gluteal/thigh based autologous reconstruction had statistically significant increase in satisfaction with breast (*Tables 3,4*).

## Psychosocial well-being

Most studies (9,14,15,20,21,25) reported statistically significant increases in psychosocial well-being with autologous reconstruction when comparing to implant reconstruction. On analysis of autologous flap choice, Jeevan *et al.* noted statistically significant increases with those undergoing immediate LD, pedicled and free TRAM, DIEP and SIEA flaps when compared to implant-based reconstruction. This was apparent in both those that underwent immediate and delayed reconstruction (*Table 3,4*).

#### Physical well-being

Half (14,15,17,25) of the studies reported statistically significant increases in physical well-being with autologous reconstruction when comparing to implant reconstruction.

Jeevan *et al.* (20) notes that although pedicled TRAM and DIEP/SIEA patients scored higher, those undergoing immediate LD and free TRAM rated their physical wellbeing worse than those undergoing implant reconstruction. If the reconstruction was delayed, all but those undergoing DIEP/SIEA flaps rated their physical well-being worse than implant-based reconstruction (*Tables 3,4*).

## Sexual well-being

Only 3 studies (9,14,20) reported statistically significant increases. Jeevan *et al.* (20) reported that regardless of immediate or delayed reconstruction, LD, pedicled, free TRAM and DIEP/SIEA flap patients reported statistically significant increases when compared to implant-based reconstruction (*Tables 3,4*).

## EORTC-QLQ-BR23/C30

Two articles by the same lead author (15,25) found that 'Physical Function' for those who underwent implant-

Table 4 Summary Jeevan et al. study results—Breast-Q

	LD	Pedicled TRAM	Free TRAM	DIEP/SIEA	Р
Jeevan et al., immediate	3	17.5	3.5	4.3	0.0001
	4.9	14.1	2.6	5.9	<0.0001
	-1.4	4.6	-1.3	1.4	0.0074
	4.3	21.1	5.1	7.1	0.003
Jeevan et al., delayed	8	2.8	14.9	13.9	<0.0001
	7.1	6.2	10.8	12.1	0.0054
	-0.4	-1.7	-0.1	4	0.0084
	4.6	5.7	15.3	12	0.0211

P values in italic indicate statistical significance. TRAM, transverse rectus abdominis muscle; LD, latissimus dorsi.

based reconstruction was higher than those who underwent autologous reconstruction, however was only statistically significant in one of the two studies. The same trend was noted in the 'Role Function' domain of the survey. No difference was detected with regards to 'Fatigue' and 'Pain' between the two reconstructive groups. A similar trend was noted regarding 'Sexual Function'. However, no statistically significant difference was noted regarding 'Body Image' between the two reconstructive groups (*Table 5*).

## SF-36

Two articles (22,23) used SF-36 questionnaires, with both noting no statistically significant difference in Physical Functioning, Bodily Pain, General Health, Social Functional or Mental Health between autologous or alloplastic reconstructive methods. One of the two studies identified a statistically significant increase in 'Vitality' when comparing expander-based reconstructions over DIEP flap-based reconstructions (*Table 6*).

# **Discussion**

With the increasing number of reconstructive options available to the patient and surgeon, and increasing survival rates of breast cancer patients, there is now an increasing number of factors outside of the surgical domain to consider for the surgeon when counseling the patient (26). This is complicated by the statistically significant heterogeneity of patients presenting, as evidenced by the baseline variables that were different between the two groups of patients

analyzed (Tables 1,2).

However, the literature is still lacking when analyzing PROMs for patients who develop complications from either autologous or alloplastic reconstruction, and was a population of patients which were excluded from most studies analyzed in this systematic review.

The BREAST-Q is a newly developed PROM questionnaire that has been validated for patients undergoing breast reconstruction to enable measurement of quality of life (QoL) and satisfaction in this population of patients (27,28). This is in comparison to EORTC QLQ-C30 and QLQ-BR23, which although are validated PROMs, are not specific for breast reconstruction. QLQ-C30 is a cancer specific health-related QoL questionnaire analyzing domains such as physical, emotional, cognitive, social functioning and sequelae of disease such as pain, nausea and fatigue, while QLQ-BR23 is a PROM validated for breast cancer patients, assessing factors such as body image, sexual functioning and enjoyment, cancer symptoms and systemic therapy side effects (29). SF-36 is a questionnaire that measures health on eight QoL domains including functional status, wellbeing and overall evaluation of health in the general population (30). This may explain why only differences between the two groups were detected by cancer specific PROMs, and only then, the results were equivocal, with only the breast-reconstruction specific BREAST-Q detecting differences between the two reconstructive techniques in some domains. This suggests that breast and reconstructive surgeons are treating a particular subset of patients that differ from other cancers, and whose perceptions and preferences for treatment

Table 5 Summary of EORTC-QLQ-BR23/C30 questionnaire results

PROM	Characteristic	Reconstruction type	Lagendijk et al., 2005–2016 study	Lagendijk et al., 2017 study
EORTC-QLQ-C30	Global Health Status	Autologous	81.3	71.5
		Implant	82.6	71.3
		Р	0.026	0.98
	Physical Function	Autologous	87.5	81.1
		Implant	92.6	82.6
		Р	<0.001	0.38
	Role Function	Autologous	83.7	72.8
		Implant	86.2	74.9
		Р	0.01	0.28
	Fatigue	Autologous	24.2	41.8
		Implant	21	30.3
		Р	0.042	0.16
	Pain	Autologous	16.1	31.1
		Implant	13.2	24.9
		Р	0.042	0.63
EORTC-QLQ-BR23	Body Image	Autologous	81.9	76.3
		Implant	77.3	72.4
		Р	0.003	0.09
	Sexual Function	Autologous	33.6	21.2
		Implant	36.6	23.4
		Р	<0.001	0.28

P values in italic indicate statistical significance.

are not adequately captured by the usual methods of determining what is important health-related QoL factors.

It is apparent that physical well-being is not significantly affected by reconstructive method, likely reflecting the fact that in the hands of a competent surgeon, alloplastic and autologous reconstruction are associated with low morbidity.

However, psychosocial well-being and satisfaction with breast are higher in autologous reconstruction compared to implant-based reconstruction, possibly due to implants not behaving like native tissue due to its synthetic nature, and unlike augmentation where normal breast tissue remains, the implant is now expected to replace the space previously occupied by normal tissue. Being an important secondary sexual organ, this new breast may not feel natural to the patient, and hence leading to the reduced psychosocial well-being and satisfaction with the breast when compared with

autologous tissue.

A limitation of this study was primarily due to the selection process of the studies analyzed, that being patients who had complications from reconstruction were in most cases excluded from the studies. Complications developed by the patient may lead to one reconstructive technique being favored over the other, something that can be conveyed to the patient, allowing for a more informed decision. Furthermore, several studies did not include subgroup analysis of autologous or alloplastic reconstruction type, hence may under or overstate the true effects reported.

Another limitation was in relation to patient numbers in each study. Only the largest study (14) consisting of 2,013 patients was able to detect statistical significance in all domains of the PROM used. It is possible other studies were not powered adequately to detect these differences.

Table 6 Summary Tønseth et al. study results—Breast-Q

SF-36 scores	Tønseth et al.						
SF-30 Scores	DIEP group	Breast implant	Р				
Physical Functioning	85	89	0.19				
Role Physical	77.5	78.7	0.89				
Bodily Pain	72.9	74.6	0.81				
General Health	78	80.4	0.69				
Vitality	60	63.8	0.55				
Social Functioning	87.3	90	0.68				
Role Emotional	75.6	69.8	0.57				
Mental Health	79.6	77.2	0.64				

#### **Conclusions**

Undergoing breast reconstruction after mastectomy has been demonstrated to be associated with positive psychological outcomes. When comparing autologous and alloplastic-based reconstruction, it is apparent from the patient perspective that autologous reconstruction is no less favorable, and in fact has a higher satisfaction of breast rate than alloplastic reconstruction techniques. Physical and sexual well-being were equivocal between the two reconstructive groups. This knowledge can be utilized by the surgeon to help council patients so they can develop a more informed individual perception, aiding in decision making and subsequently improved QoL.

# **Acknowledgments**

None.

## **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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Cite this article as: Phan R, Hunter-Smith DJ, Rozen WM. The use of Patient Reported Outcome Measures in assessing patient outcomes when comparing autologous to alloplastic breast reconstruction: a systematic review. Gland Surg 2019;8(4):452-460. doi: 10.21037/gs.2019.07.04

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