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Patient-Reported Outcome Measures In Patients With Clinical T4 Breast Cancer Treated With Mastectomy With and Without Reconstruction

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Abstract

Introduction: Patients with clinical T4M0 breast cancer are recommended to undergo neoadjuvant chemotherapy, modified radical mastectomy, and postmastectomy radiotherapy. Here we determine if BREAST-Q scores differ by decision to pursue reconstruction or timing of reconstruction.

Methods: Retrospective, single institutional study of cT4 breast cancer patients from 2014-2021 without evidence of distant metastatic disease undergoing mastectomy with or without reconstruction. BREAST-Q was administered as routine care preoperatively, and 6 months, 1 year, and 2 years postoperatively. Satisfaction and quality of life domains were compared between mastectomy with no reconstruction (NR), immediate reconstruction (IR), and delayed reconstruction (DR) groups.

Results: 144 patients were eligible: 71 (49%) had NR; 36 (25%) had DR; 37 (26%) had IR. Patients undergoing reconstruction were younger and more likely to elect contralateral prophylactic mastectomy. Timing of reconstruction was not associated with significant differences in satisfaction with breasts (SATBR) at any timepoint. For patients having DR, breast satisfaction increased over time following reconstructive surgery. Physical well-being of the chest (PWB-CHEST) did not significantly differ between IR, DR, or NR, at any timepoint. Patients undergoing DR experienced improvement in PWB-CHEST from preoperative scores; patients with IR and NR experienced PWB-CHEST decline over time. Psychosocial well-being (PSWB) did not significantly differ across time or by subgroup.

Conclusions: Patients with T4 breast cancer who elected reconstruction had no difference in patient-reported outcomes based on timing of reconstruction. In the DR cohort, SATBR significantly improved following reconstructive surgery. These data can help inform breast reconstructive decision making for patients facing the choice between DR, IR, and NR.

INTRODUCTION

Clinical stage T4 breast cancer is defined as any breast tumor, regardless of size, with direct extension into the chest wall, breast skin resulting in edema or erythema, or inflammatory breast cancer (IBC).¹ Clinical T4 breast cancer is thought to represent a unique subset of breast cancer associated with a more aggressive clinical nature and poorer outcomes compared to earlier-stage breast cancer, so trimodality therapy—neoadjuvant chemotherapy, modified radical mastectomy, and postmastectomy radiotherapy (PMRT)—is currently standard of care for clinical stage T4 breast cancer with no evidence of distant metastatic disease.²⁻⁴ For these patients, however, the impact of breast reconstruction, immediate or delayed, on satisfaction and quality of life after mastectomy is not well understood.

Many patients with T4 breast cancer do not undergo reconstruction. For patients with clinical stage T4d (inflammatory breast carcinoma) breast cancer, reconstruction has also been associated with a higher risk of complications and delays in radiotherapy.⁵ For T4d patients, therefore, an initial flat closure without reconstruction is the standard of care.⁴⁻⁷ Even for non-IBC T4a-c patients, most patients elect to postpone or forego reconstruction to decrease risk for complications and potential delays in adjuvant therapy.^{5,8} Ultimately, among women with T4 breast cancer who underwent an initial flat closure, less than 20% choose to have reconstruction.⁵ Multiple studies have shown that breast reconstruction significantly improves long-term patient satisfaction and quality of life, although PMRT has been independently associated with lower breast satisfaction among women undergoing implant-based reconstruction and autologous reconstruction.^{9,10} However these studies focused primarily on non-T4 patients, so the breast reconstruction experience of T4 patients is lacking in current literature.

In this study, we utilize the BREAST-Q, a validated patient-reported outcome measure (PROM) for satisfaction and quality of life after breast surgery,¹¹⁻¹³ to determine whether patient satisfaction and quality of life differs among T4 patients based on their decision to pursue reconstruction and the timing of reconstruction.

METHODS

Following approval from the Memorial Sloan Kettering Cancer Center institutional review board, we performed a retrospective cohort study of patients diagnosed with clinical stage T4 breast cancer without evidence of distant metastatic disease between 2014-2021 who underwent mastectomy with IR, DR, or NR. BREAST-Q is routinely requested for all patients undergoing mastectomy at our institution. For this cohort, all patients were eligible and requested to complete the BREAST-Q at baseline and at 6 months, 1 year, and 2 years postoperatively. The BREAST-Q was routinely administered via an electronic portal as well as offered in clinic using an institutionally approved electronic tablet. Patients did not have

to have complete BREAST-Q questionnaires at all time points and for all domains to be included in the study. All available data at each time point and domain were included when completed.

Complete BREAST-Q data were obtained from an institutional database. Domains of the BREAST-Q examined included satisfaction with breasts (SATBR), physical well-being of the chest (PWB-CHEST) and psychosocial well-being (PSWB). Each domain was scored on a scale of 0-100. Higher scores on a 0-100 scale indicated superior satisfaction. SATBR is validated for patients who undergo reconstruction after mastectomy, but not for those who elect flat closure. A minimum 3-point difference was considered clinically important for PWB-CHEST and 4-point difference was considered clinically important for SATBR and PSWB.¹⁴ We compared median SATBR, PWB-CHEST, and PSWB scores between mastectomy with IR, DR, and NR groups at baseline, 6 months, 1 year, and 2 years postoperatively. Postoperative timing was defined as after reconstruction in patients undergoing delayed reconstruction, or from the index operation (mastectomy) if no reconstruction or immediate reconstruction were performed.

Clinicopathologic and treatment data were collected from an institutional tumor registry and from medical records. Demographic and clinicopathologic data including age at surgery, race/ethnicity, body mass index (BMI: kg/m²), clinical and pathologic tumor and nodal stage, performance of contralateral prophylactic mastectomy (CPM), and receipt of radiotherapy and chemotherapy were collected. Characteristics were compared between NR, IR, and DR, using Fishers' exact test for categorical variables and the Kruskal-Wallis test for continuous variables. Multiple comparison correction was done using the Benjamini Hochberg procedure. Univariate analysis was performed to compare patient and tumor characteristics among the groups.

Available BREAST-Q data at all time points were included in the analysis. Median (interquartile range [IQR]) scores were reported for the NR, IR, and DR cohorts at baseline, 6 months, 1 year, and 2 years. Mean preoperative scores were also reported for the NR, IR, and DR cohorts, and the difference from baseline mean scores were reported at 6 months, 1 year and 2 years. Boxplots were created to assess trends in scores over time for each group.

RESULTS

144 patients with T4 breast cancer without evidence of distant metastatic disease were included in the study. Seventy-one (49.3%) underwent mastectomy without reconstruction (NR) and 73 (50.7%) underwent mastectomy with reconstruction. Of those who elected reconstruction, 36 (49.3%) had delayed reconstruction (DR) and 37 (50.7%) had immediate reconstruction (IR). In those who elected delayed reconstruction; 12 (25%) had reconstruction 6-12 months after initial surgery, 7 (14.6%) had reconstruction 12-18 months after initial surgery, 7 (14.6%) had reconstruction 18-24 months after initial surgery, and 3 (6.2%) had reconstruction greater than 24 months after initial surgery. All patients in the IR group had tissue expanders placed at the initial surgery. Following the initial surgery, 13 of 37 (35.1%) went on to have autologous reconstruction and 24 of 37 (64.9%) had

implant reconstruction. In the delayed reconstruction group, all patients had autologous reconstruction.

Most patients identified as non-Hispanic (82%) and were White (67%); 17% self-identified as Black/African American and 10% as Asian. Race and ethnicity were similar across NR, IR, and DR cohorts. The median age was 52 years (range 24-88) and the median BMI was 28.2 (range 17.3-54.7). Patients undergoing reconstruction were younger than patients who elected NR (median 49 versus 55 years, $p < 0.001$). All patients undergoing IR or DR received neoadjuvant chemotherapy, and 2 patients in the NR cohort declined chemotherapy. All patients received PMRT except 1 patient in the immediate reconstruction cohort who refused radiation therapy. Patients undergoing immediate reconstruction were more likely to elect CPM as compared to the DR and NR cohorts, (27% versus 8.3% versus 11%, $p = 0.058$). Patients with IBC were less likely to undergo IR as compared to DR and NR (5.4% versus 47% versus 61, $p < 0.001$)(Table 1).

Among patients undergoing reconstruction after mastectomy, there were no statistically significant differences in SATBR between delayed and immediate reconstruction at any time point (Fig. 1). Six months after reconstruction, SATBR median scores were 57 versus 58 for DR versus IR, respectively ($p = 0.2$); 2 years after reconstruction, SATBR median scores were 64 versus 58 for DR versus IR, respectively ($p = 0.3$)(Table 2). When examining the trend in SATBR over time, patients who elected DR had an increase in median SATBR score over time following reconstructive surgery, with a median preoperative score of 46 compared to a 2-year median postoperative score of 64. In patients electing immediate reconstruction, SATBR scores remained similar over time (Table 2) with no statistically significant change in mean SATBR score at 2 years ($p = 0.87$)(Table 3). Delayed reconstruction patients had a statistically significant increase in mean SATBR scores after reconstruction (2 years post-op – pre-op: +18.6, $p < 0.001$)(Table 3).

PWB-CHEST did not significantly differ between IR, DR, or NR at any time point (Fig. 2). Patients undergoing DR were noted to have a trend in improving PWB-CHEST scores from preoperative score to 2-year post-operative scores (median scores 66 versus 76), while patients with IR and NR experienced a decline in PWB-CHEST over time (median scores 74 versus 66 and 78 versus 64, respectively), although these were not found to be statistically significant. A statistically significant decline in mean PWB-CHEST scores was noted in the IR group at both 6 months and 1 year after surgery (-11.44 and -11.73 , respectively, $p = 0.03$). Additionally, PSWB did not significantly differ between IR, DR, or NR at any time point (Fig. 3) and, over time, there was no significant change in PSWB (Table 2).

DISCUSSION

In this preliminary study evaluating BREAST-Q scores among clinical T4 breast cancer patients undergoing mastectomy with NR, DR, or IR, neither the decision to pursue reconstruction nor the timing of reconstruction was associated with superior patient-reported outcomes. However, patients who underwent delayed reconstruction did experience significantly improved breast satisfaction after surgery.

Although cT4 breast cancer is a locally advanced and often aggressive presentation of breast cancer, as therapy continues to improve and patients are living longer, patients' satisfaction with outcomes becomes an even more important consideration. Immediate reconstruction compared to delayed reconstruction was not associated with superior outcomes for breast satisfaction at any time point in this study. However, when examined longitudinally, patients in the DR cohort experienced a significant improvement in breast satisfaction scores at both 6 months and 2 years postoperatively, compared to their preoperative baseline scores. Patients who underwent IR did not experience a significant change in breast satisfaction scores at any postoperative timepoint compared to their preoperative baseline scores. Similarly, in a cohort of 175 patients from the Mastectomy Reconstruction Outcomes Consortium (MROC), Billig et al. reported patients undergoing PMRT with both delayed and immediate autologous reconstruction had equivalent satisfaction outcomes determined by BREAST-Q scores taken at 1 and 2 years postoperatively.¹⁵ These data suggest that patients who desire reconstruction can expect an improvement in their breast satisfaction following DR to, ultimately, a level similar to those who elect IR.

Prior studies have demonstrated increased complication rates in T4 patients pursuing IR,⁵ as well as some delays to postoperative therapy,^{16,17} suggesting that patients should be counseled regarding this risk when discussing timing of reconstruction. The risk of complications and delays in adjuvant therapy was prohibitively high among IBC patients (46%), and the standard recommendation for this group remains NR at the time of initial surgery.⁵ Over the past few years, there have been an increasing number of women who elect to forego reconstruction and "go flat". A recent study utilizing an online survey of 931 women who elected NR reported a mean scaled satisfaction score of 3.72 (out of 5), suggesting that many women are satisfied with the decision to avoid reconstruction.¹⁸ A limitation of our study is that the BREAST-Q was not designed to assess breast satisfaction in women who elected no reconstruction. Therefore, this group was not included in analyses regarding breast satisfaction. Further efforts to assess satisfaction for the NR patients can help to inform shared decision making for clinical T4 breast cancer patients.

PWB-CHEST scores did not differ between the NR, DR, and IR cohorts at any time point. However, when assessing mean scores over time, both the NR and IR groups had decreased mean scores compared to preoperative baseline at 6 months. As all patients in the NR and IR groups received PMRT immediately following surgery, this decline likely reflects the impact of radiotherapy on PWB-CHEST. Similarly, in a study of 3268 patients undergoing mastectomy with reconstruction, patients who received postoperative radiation had poorer PWB-CHEST scores up to 3 years after surgery. This study suggests that the untoward effects of radiotherapy on the PWB-CHEST are not mitigated by reconstruction.¹⁹ In the group that elected delayed reconstruction, PWB-CHEST did not significantly change following surgery. Importantly, this group underwent PMRT prior to reconstructive surgery further supporting the association between radiation and PWB-CHEST.

Recently, 2 studies have demonstrated the safety of preoperative radiotherapy followed by skin-sparing mastectomy with autologous reconstruction.^{20,21} A clinical trial examining the feasibility and safety of neoadjuvant radiotherapy followed by conventional modified radical mastectomy with autologous reconstruction among women with non-metastatic clinical T4

breast cancer is ongoing.²² The impact of this novel approach on patient-reported outcomes will be an important secondary aim of this trial to help inform shared decision making.

The present study is, to our knowledge, the first to assess if BREAST-Q scores differ among patients with T4 breast cancer undergoing mastectomy with and without reconstruction. Its limitations include the retrospective design and the potential for selection bias as patients pursued the reconstruction of their choice in discussion with their physician. Furthermore, the breast satisfaction domain of the BREAST-Q is only validated for women with reconstruction. Tools to better assess satisfaction among women without reconstruction are needed. As there are a growing number of patients who do not desire reconstruction,¹⁸ and as there is not yet a tool designed to specifically assess satisfaction among this cohort of patients, it is feasible that we are under-representing the patient experience in those who do not pursue reconstruction, as the BREAST-Q is not validated in those without reconstruction.

Conclusions

In patients with T4 breast cancer, timing of reconstruction was not associated with differences in outcomes for SATBR, PWB-CHEST, or PSWB at any time point. In the DR cohort, there was improvement in SATBR through 2 years postoperatively. These data can help to inform breast reconstructive decision making for patients facing the choice between DR, IR, and NR. Novel strategies to improve outcomes for these patients are needed.

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Synopsis:

Aim:

Do PROMs differ among clinical T4 patients undergoing mastectomy with and without reconstruction?

Findings:

Neither reconstruction nor timing of reconstruction were associated with superior outcomes for breast satisfaction, physical well-being of the chest, or psychosocial well-being at any timepoint.

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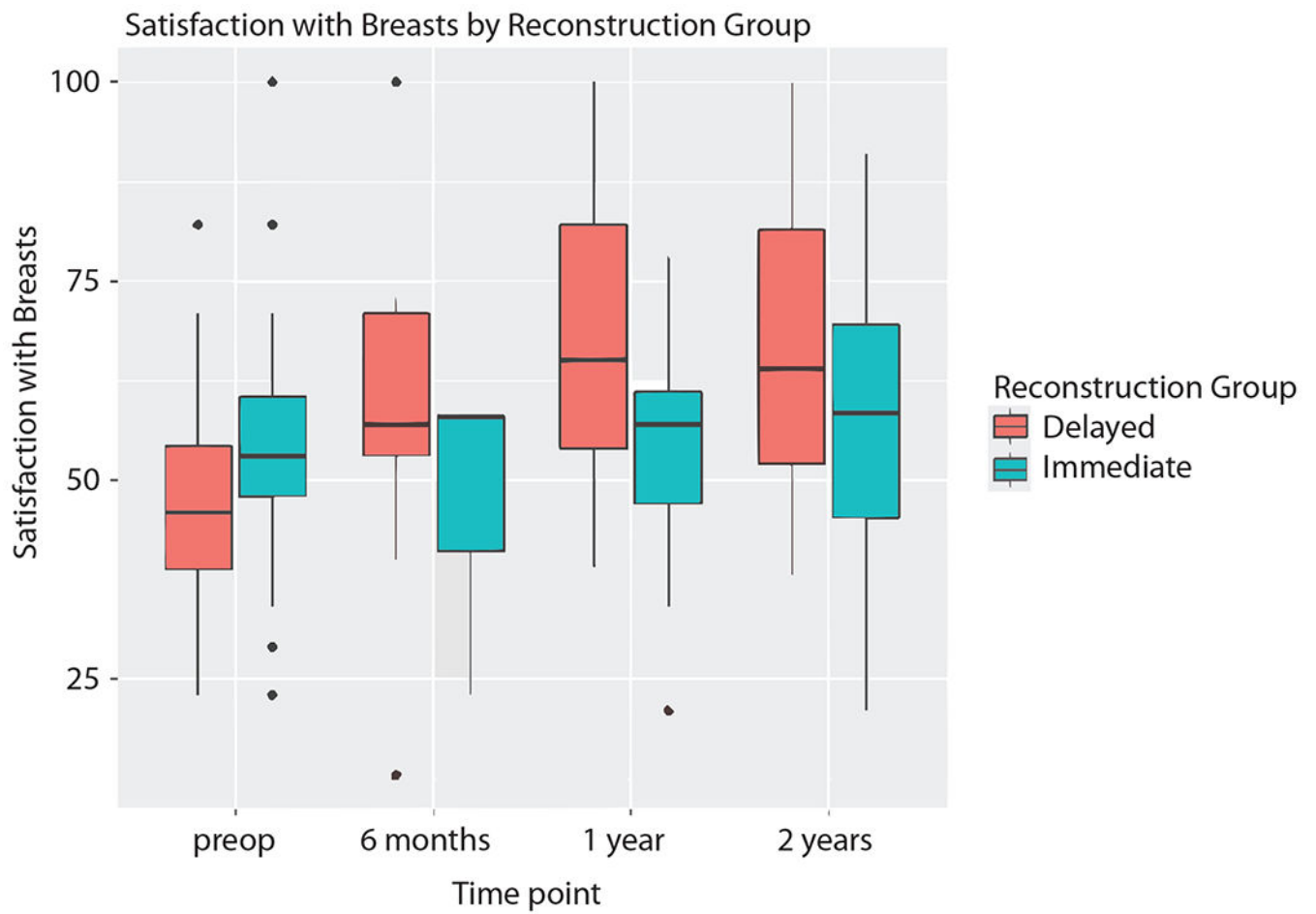


Fig. 1. Satisfaction with breasts scores in the delayed reconstruction and immediate reconstruction cohorts.

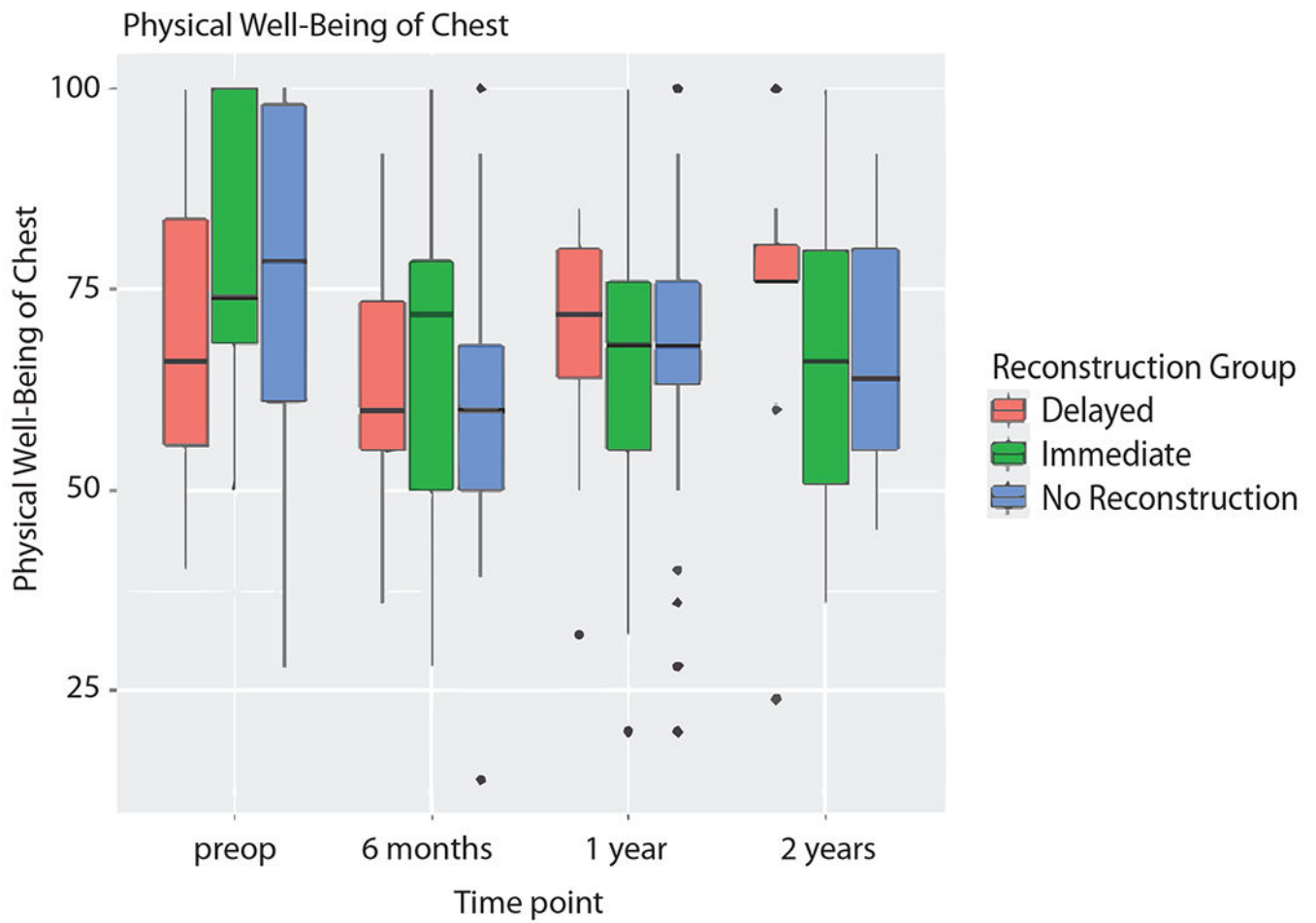


Fig 2. Physical well-being of the chest scores in the no reconstruction, delayed reconstruction, and immediate reconstruction cohorts.

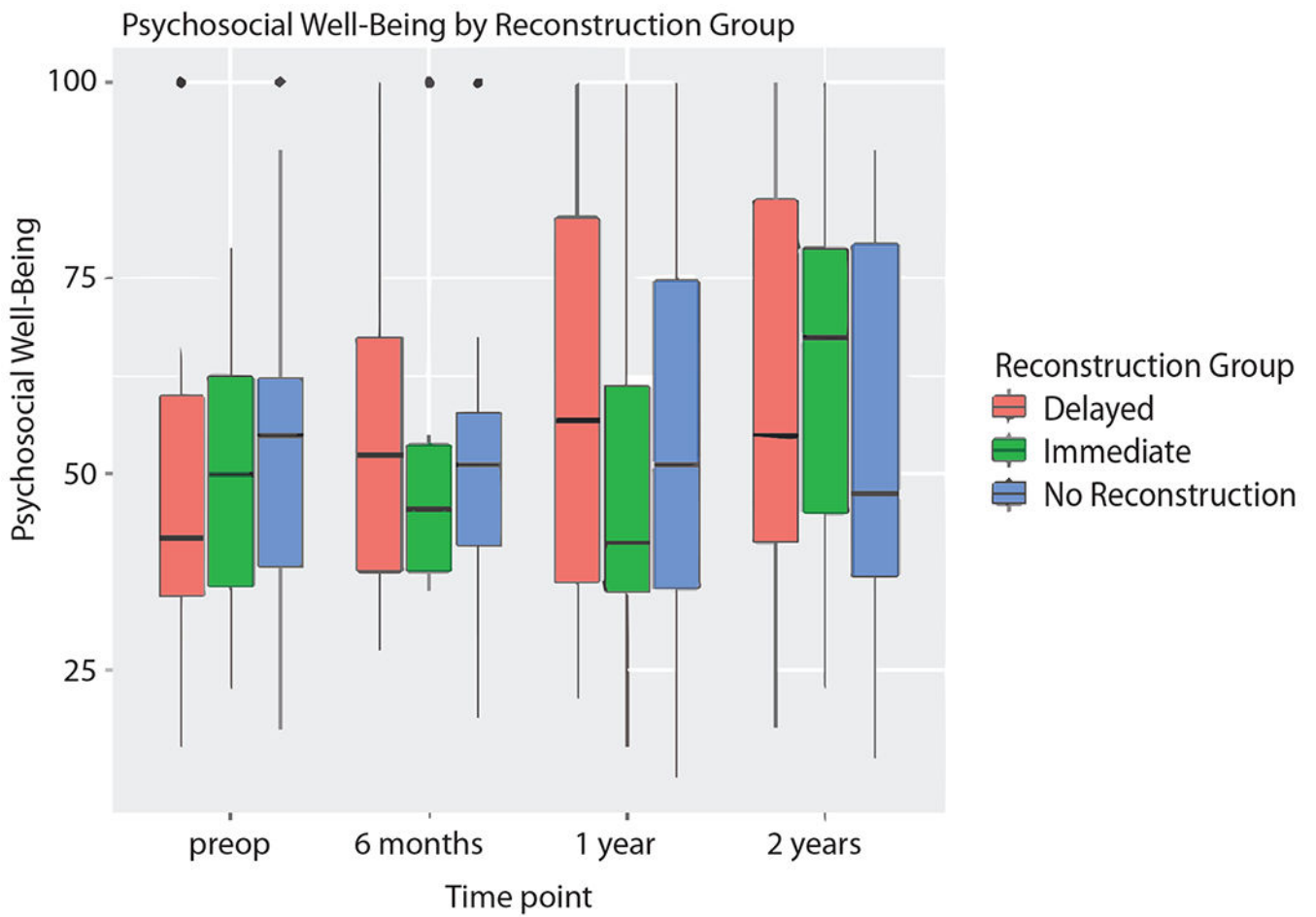


Fig 3. Psychosocial well-being scores in the no reconstruction, delayed reconstruction, and immediate reconstruction cohorts.

TABLE 1

Patient, tumor, and treatment characteristics in the delayed, immediate, and no reconstruction cohorts

Characteristic	Reconstruction				p-value ^I
	Overall, n = 144	Delayed, n = 36	Immediate, n = 37	None, n = 71	
Median Age, years	51	51	47	55	< 0.001
Median BMI	28.2	30.0	27.7	26.4	0.13
Race, n(%)					> 0.9
Asian-Far East/Indian Subcont	15 (10%)	3 (8.3%)	4 (11%)	8 (11%)	
Black or African American	24 (17%)	6 (17%)	8 (22%)	10 (14%)	
Other	3 (2.1%)	1 (2.8%)	0 (0%)	2 (2.8%)	
White	96 (67%)	25 (69%)	24 (65%)	47 (66%)	
Unknown	6 (4.2%)	1 (2.8%)	1 (2.7%)	4 (5.6%)	
Ethnicity, n (%)					0.5
Hispanic or Latino	14 (9.7%)	4 (11%)	2 (5.4%)	8 (11%)	
Non-Hispanic	118 (82%)	31 (86%)	32 (86%)	55 (77%)	
Unknown	12 (8.3%)	1 (2.8%)	3 (8.1%)	8 (11%)	
Inflammatory					< 0.001
No	82 (57%)	19 (53%)	35 (95%)	28 (39%)	
Yes	62 (43%)	17 (47%)	2 (5.4%)	43 (61%)	
Clinical N, n (%)					0.3
N0	17 (12%)	5 (14%)	8 (22%)	4 (5.6%)	
N1	98 (68%)	24 (67%)	23 (62%)	51 (72%)	
N2	12 (8.3%)	2 (5.6%)	3 (8.1%)	7 (9.9%)	
N3	17 (12%)	5 (14%)	3 (8.1%)	9 (13%)	
Pathologic T, n (%)					0.019
T0	48 (33%)	21 (58%)	7 (19%)	20 (28%)	
T1	39 (27%)	4 (11%)	15 (41%)	20 (28%)	
T2	27 (19%)	4 (11%)	9 (24%)	14 (20%)	
T3	7 (4.9%)	2 (5.6%)	1 (2.7%)	4 (5.6%)	
T4	23 (16%)	5 (14%)	5 (14%)	13 (18%)	
Pathologic, n (%)					0.4
N0	65 (45%)	20 (56%)	16 (43%)	29 (41%)	
N1	37 (26%)	8 (22%)	12 (32%)	17 (24%)	
N2	25 (17%)	7 (19%)	5 (14%)	13 (18%)	
N3	17 (12%)	1 (2.8%)	4 (11%)	12 (17%)	
CPM, n (%)					0.058
Yes	21 (15%)	3 (8.3%)	10 (27%)	8 (11%)	
No	123 (85%)	33 (92%)	27 (73%)	63 (89%)	
Radiation, n (%)					0.5

Characteristic	Overall, n = 144	Reconstruction			p-value ^I
		Delayed, n = 36	Immediate, n = 37	None, n = 71	
Yes	143 (99%)	36 (100%)	36 (97%)	71 (100%)	
No	1 (0.7%)	0 (0%)	1 (2.7%)	0 (0%)	
Chemotherapy, n (%)					0.8
Neoadjuvant	141 (98%)	36 (100%)	37 (100%)	68 (96%)	
Adjuvant	1 (0.7%)	0 (0%)	0 (0%)	1 (1.4%)	
None	2 (1.4%)	0 (0%)	0 (0%)	2 (2.8%)	
Reconstruction Type, n (%)					
TE/Implant		0 (0%)	24 (64.9%)	NA	
Autologous		36 (100%)	13 (35.1%)	NA	

^IStatistical tests performed: Kruskal-Wallis test and Fisher's exact test

Abbreviations: *BMI* body mass index, *Subcont* subcontinent, *CPM* contralateral prophylactic mastectomy, *NA* not available

TABLE 2

Median (IQR) SATBR, PWB-CHEST, and PSWB scores by type of reconstruction

	Delayed Reconstruction	Immediate Reconstruction	No Reconstruction	p-value ^I
SATBR scores, median (IQR)				
Preoperative	46 (39, 54)	53 (48, 60)		0.2
6 month*	57 (53, 71)	58 (41, 58)		0.2
1 year*	65 (54, 82)	57 (47, 61)		0.079
2 year*	64 (52, 82)	58 (45, 70)		0.3
PWB-CHEST scores, median (IQR)				
Preoperative	66 (56, 84)	74 (68, 100)	78 (61, 98)	0.092
6 month*	60 (55, 74)	72 (50, 78)	60 (50, 68)	0.3
1 year*	72 (64, 80)	68 (55, 76)	68 (63, 76)	0.5
2 year*	76 (76, 80)	66 (51, 80)	64 (55, 80)	0.4
PSWB scores, median (IQR)				
Preoperative	54 (48, 68)	60 (48, 70)	64 (50, 70)	0.8
6 month*	62 (50, 74)	56 (50, 63)	61 (53, 66)	0.9
1 year*	66 (49, 86)	53 (48, 69)	61 (48, 80)	0.4
2 year*	64 (53, 88)	74 (56, 83)	58 (50, 84)	0.9

^IStatistical tests performed: Kruskal-Wallis test and Wilcoxon rank sum test

* indicates time from reconstruction if performed

Abbreviations: *IQR* interquartile range, *SATBR* satisfaction with breasts, *PWB-CHEST* physical well-being of the chest, *PSWB* psychosocial well-being

TABLE 3

Summary of BREAST-Q scores prior to reconstruction and at 6 months, 1 year, and 2 years after reconstruction

	Preoperative Mean (SE)	Difference in Mean from Preop to 6 months (SE) (n)	p-value*	Difference in Mean from Preop to 1 year (SE) (n)	p-value*	Difference in Mean from Preop to 2 year (SE) (n)	p-value*
Delayed Reconstruction							
SATBR	48.5 (4.0)	16.3 (3.6) (13)	< 0.001	18.0 (3.8) (12)	< 0.001	18.6 (4.3) (10)	< 0.001
PWB-CHEST	66.8 (3.1)	-2.24(3.3) (15)	0.59	4.53 (3.5) (12)	0.30	6.05 (4.0) (10)	0.28
PSWB	61.5 (3.9)	5.05 (3.7) (14)	0.31	9.7 (4.0) (11)	0.11	7.98 (4.6) (9)	0.28
Immediate Reconstruction							
SATBR	55.4 (4.2)	-4.39 (7.2) (4)	0.87	2.07 (5.9) (7)	0.87	1.81 (5.2) (10)	0.87
PWB-CHEST	76.4 (4.1)	-11.44 (4.3) (16)	0.03	-11.73 (4.2) (18)	0.03	-8.58 (4.6) (11)	0.14
PSWB	63.5 (4.1)	0.81 (6.8) (14)	0.91	-2.72 (5.4) (7)	0.74	4.81 (4.7) (10)	0.74
No Reconstruction							
PWB-CHEST	73.3 (3.4)	-13.0 (3.8) (11)	0.008	-5.85 (3.7) (10)	0.18	-9.43 (5.0) (4)	0.13
PSWB	65.4 (2.9)	-4.8 (2.8) (11)	0.45	-3.79 (2.7) (10)	0.45	-4.47 (3.6) (4)	0.45

* adjusted for multiple comparison correction

Abbreviations: *Preop* preoperative, *SATBR* satisfaction with breasts, *PWB-CHEST* physical well-being of the chest, *PSWB* psychosocial well-being, *SE* standard error