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Impact of Unilateral versus Bilateral Breast Reconstruction on Procedure Choices and Outcomes

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Abstract

Background: In choosing between implant-based and autologous breast reconstruction, surgeons and patients must weigh relative risks and benefits. However, differences in outcomes across procedure types may vary between unilateral versus bilateral reconstructions. Procedure-related differences in complications and patient-reported outcomes (PROs) were evaluated for unilateral and bilateral reconstruction.

Methods: Complications and PROs were assessed at two years for patients undergoing autologous (TRAM, DIEP, SIEA) or implant-based (TE, DTI) reconstructions. Overall complications and major complications (requiring re-admission and/or re-operation) were recorded, while PROs were measured with BREAST-Q and PROMIS surveys. Stratified regression models compared outcomes between autologous and implant-based reconstructions, separately for unilateral and bilateral cohorts.

Results: Among 2125 patients, 917 underwent unilateral (600 implant, 317 autologous) and 1208 underwent bilateral (994 implant, 214 autologous) reconstructions. Controlling for patient characteristics, complication rates were significantly higher in the autologous versus implant-based group with both unilateral (overall: OR 2.50, $p < 0.001$; major: OR 2.19, $p = 0.001$) and bilateral (overall: OR 2.13, $p < 0.001$; major: OR 1.69, $p = 0.014$) cohorts. In unilateral reconstruction, the autologous group demonstrated significantly better PROs compared to the implant-based group in satisfaction with breast (mean difference=9.85, $p < 0.001$), psychosocial well-being (mean difference=4.84, $p = 0.006$), and sexual well-being (mean difference=11.42, $p < 0.001$). In bilateral reconstruction, the autologous group demonstrated significantly higher PROs only for satisfaction with breast (mean difference=5.13, $p = 0.001$).

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Conclusions: Although autologous reconstruction is associated with significantly better PROs compared to implant-based techniques in unilateral reconstruction, procedure choice has far less impact in bilateral reconstruction. Autologous procedures have higher complications rates in both unilateral and bilateral settings.

Introduction

When choosing between implant-based and autologous flap breast reconstruction, surgeons and patients routinely weigh relative risks and benefits. Previous studies suggest that autologous flap breast reconstruction is superior to implant-based breast reconstruction in delivering long-term aesthetic outcomes, patient satisfaction, and quality of life (1–4). Autologous breast reconstruction can mimic the natural breast, maintain more stable aesthetic results over time, and avoid long-term implant-associated complications such as capsular contracture, age-related deterioration, and vulnerability in weight fluctuation. However, analysis of complication rates and clinical outcomes between procedure types yield different results depending on whether breast reconstruction is performed unilaterally versus bilaterally.

The rate of bilateral breast reconstruction has increased as more women with unilateral breast cancer pursue contralateral prophylactic mastectomies and gene carriers pursue bilateral risk-reducing mastectomies. Prophylactic mastectomy reduces the risk of breast cancer by 90% in both women with BRCA1/2 mutations and in women with a strong family history alone (5, 6). In particular, younger women have elected to pursue bilateral risk-reducing mastectomies, with the greatest rates observed in young women with a BRCA mutation, HER2 positivity, large tumor size, node involvement, or fear of recurrence(7). Additionally, unilateral breast cancer that presents with a higher stage of disease is associated with bilateral mastectomy(8). Overall, the rate of bilateral mastectomy in breast cancer patients increased nearly three-fold from 2005 to 2012(3). Given the increased rate of bilateral mastectomies, the optimal method of breast reconstruction for both bilateral and unilateral reconstruction deserves greater focus. Despite evidence demonstrating superior outcomes with autologous breast reconstruction, implant-based breast reconstruction is more commonly performed in bilateral cases, where achieving symmetry with the native contralateral breast is not a consideration. Although potential differences may exist in the relative complication rates and long-term clinical outcomes when specific reconstructive methods are performed unilaterally versus bilaterally, no prior study has examined whether performance of unilateral versus bilateral breast reconstruction should be a significant consideration when making reconstructive procedure choices.

Our study evaluates the impact of unilateral versus bilateral breast reconstruction on reconstruction procedure choices and clinical outcomes utilizing data from the Mastectomy Reconstruction Outcomes Consortium (MROC) study. The goals of this study were to compare (1) the overall and major complications and (2) patient-reported outcomes (PROs) between autologous flap and implant-based reconstructions stratified by immediate unilateral and bilateral breast reconstruction.

Methods:

Study Population

Patients were recruited from the Mastectomy Reconstruction Outcomes Consortium (MROC), a multicenter prospective cohort study of patients undergoing mastectomy reconstruction at 11 institutions in the United States (District of Columbia, Georgia, Illinois, Massachusetts, Michigan, New York, Ohio, Texas) and Canada (British Columbia, Manitoba) over 5 years (2012–2017). Institutional Review Board (IRB) or Research Ethics Board (REB) approvals were obtained from participating sites.

All patients who underwent immediate breast reconstruction with autologous flap or implant-based techniques were included. Autologous flap reconstructions included transverse rectus abdominis (TRAM) flap, deep inferior epigastric perforator (DIEP) flap, or superficial inferior epigastric artery (SIEA) flap reconstruction. Implant-based breast reconstructions included tissue expander (TE) or direct-to-implant (DTI) reconstruction. The patient population then was subdivided into unilateral or bilateral reconstruction subgroups. Both prophylactic and therapeutic mastectomies were included. All patients completed at least two-years of post-operative follow-up. Patients were excluded if they underwent mixed implant and autologous reconstruction (e.g. unilateral reconstruction with latissimus flap plus implant; or bilateral reconstruction with autologous flap on one side and implant-based reconstruction on the other side), delayed or delayed-immediate reconstruction, or bilateral reconstruction with mixed timing (e.g. immediate on one side and delayed on the other side).

Data Collection

Demographic and clinical characteristics of patients were collected, including age, body mass index (BMI), smoking status (non-smoker, prior smoker, current smoker), diabetes mellitus, laterality (unilateral vs. bilateral), mastectomy indication (therapeutic vs. prophylactic), mastectomy type (simple or modified radical vs. nipple sparing), reconstruction timing (immediate vs. delayed), reconstruction type (autologous vs. implant-based), radiation (none, pre-mastectomy, post-reconstruction), and adjuvant chemotherapy. Data on contralateral symmetry procedures were collected for unilateral breast reconstruction patients which included augmentation, mastopexy, and reduction.

Surgical complications were compiled at two-years postoperatively through electronic medical record (EMR) review. Complications were analyzed separately in terms of (1) overall complication rates and (2) major complication rates, with major complications defined as those requiring readmission and/or reoperation. Complications observed in both flap and implant-based reconstruction included hematoma, seroma, infection, wound dehiscence, and hypertrophic or keloid scarring. Flap-specific complications included partial flap loss, total flap loss, fat necrosis, abdominal hernia or bulge, and donor-site wound dehiscence. Implant-based breast reconstruction-specific complications included explantation. For unilateral reconstructions, complication data analyzed was specific to the reconstructed breast and/or donor site (if applicable) and did not include complications from the contralateral symmetry procedure.

Patient-reported outcomes (PROs) were measured through the validated BREAST-Q breast reconstruction module and the validated Patient-Reported Outcomes Measurement Information System (PROMIS) surveys (9, 10). Data from both surveys were collected preoperatively and two-years postoperatively. The BREAST-Q breast reconstruction module measured patient satisfaction with the breast, psychosocial well-being, physical well-being, and sexual well-being. Responses were quantified using Q-score software. The PROMIS survey was utilized to evaluate physical well-being. Only patients with successfully completed reconstructions were included for PRO analysis per the original MROC study protocol.

Statistical Analysis

Patient characteristics were compared by procedure type (implant-based vs. autologous), stratified by laterality (unilateral vs. bilateral), using Student's t-test for continuous variables and chi-square tests for categorical factors. Two-year postoperative complication rates and PROs were evaluated between two procedure groups for unilateral and bilateral reconstruction, respectively. Mixed-effects regression models with study centers as random intercepts were used to further compare outcomes of patients across procedure groups. Patient-reported outcome scores at the two-year post-reconstruction time point were missing for some patients. To reduce potential bias, multiple imputations with chained equations were employed to create 10 complete imputed datasets. The regression models specified above were fit for each imputed data set. The results were then combined using Rubin's rule. We reported adjusted odds ratios (ORs) for complications and Beta coefficients for PROs, with 95% confidence intervals (CI) and corresponding p-values. Statistical analysis was performed with SAS 9.4 (SAS Institute, Cary, NC) with statistical significance of 0.05.

Results:

Patient Characteristics

A total of 2125 patients were included, with 917 patients undergoing unilateral breast reconstruction (600 implant, 317 autologous) and 1208 undergoing bilateral breast reconstruction (994 implant, 214 autologous). Average age was 49.1 years (implant unilateral: 52.5; autologous unilateral: 52.7; implant bilateral: 45.9; autologous bilateral: 49.8; $p < 0.001$). Patients who underwent bilateral breast reconstruction with implant-based techniques were significantly younger than those who underwent autologous flap reconstruction ($p < 0.001$). Average BMI was 26.5 (implant unilateral: 26.2; autologous unilateral: 28.3; implant bilateral: 25.3; and autologous bilateral: 30.0; $p < 0.001$). Patients who underwent implant-based breast reconstruction had significantly lower BMIs than those who underwent autologous flap reconstruction for both unilateral ($p < 0.001$) and bilateral ($p < 0.001$) reconstruction. Contralateral procedures were performed on 59.5% of unilateral implant-based reconstruction patients and 45.1% of unilateral autologous flap reconstruction patients. The implant-based reconstruction group had a higher rate of nipple-sparing mastectomies compared to the autologous reconstruction group in both unilateral and bilateral reconstruction settings ($p < 0.001$). Table 1 further summarizes patient characteristics by type and laterality of reconstruction performed.

Complications

Unilateral Reconstruction—Two-year overall complication rates and major complication rates were significantly higher for patients undergoing unilateral autologous flap reconstruction compared to unilateral implant-based reconstruction (overall: 46.4% vs. 24.2%, $p<0.001$; major: 27.4% vs. 17.5%, $p<0.001$) (Table 2). Multivariable analysis demonstrated that autologous flap reconstruction was associated with significantly higher overall complications (OR 2.50, $p<0.001$) and major complications (OR 2.19, $p=0.001$) compared to implant-based breast reconstruction (Table 3). However, autologous reconstruction was associated with a significantly lower risk of reconstruction failure, defined as loss of implant or total flap loss, compared to implant-based reconstruction (OR 0.12, $p<0.001$). Not surprisingly, increasing age, BMI, active smoking, and post-mastectomy radiotherapy were associated with significantly higher complication rates. Table 3 summarizes the multivariate analysis results for two-year complications.

Bilateral Reconstruction—Similar to the findings for unilateral breast reconstruction, bilateral breast reconstruction two-year complication rates were significantly higher for autologous flap reconstruction compared to implant-based reconstruction in terms of both overall complications (57.5% vs. 28.9%, $p<0.001$) and major complications (37.9% vs. 21.6%, $p<0.001$) (Table 2). Again, multivariable analysis showed autologous flap reconstruction to be associated with significantly higher risk of overall (OR 2.13, $p<0.001$) and major complications (OR 1.69, $p=0.014$) compared to implant-based reconstruction (Table 4). Similar to findings in the unilateral reconstruction group analysis, bilateral breast reconstruction patients with autologous reconstruction had lower rates of reconstructive failure compared to patients undergoing implant-based reconstruction (OR 0.14, $p=0.001$). Increasing BMI, current smoking, and both pre-reconstruction and post-reconstruction radiotherapy were associated with a significantly increased risk of reconstruction failure (Table 4).

Patient-Reported Outcome Measures

Patient-reported outcomes (PROs) measured through the BREAST-Q breast reconstruction module evaluated patient satisfaction with the breast, psychosocial well-being, physical well-being, and sexual well-being. Tables 5 summarizes the unadjusted PRO scores from BREAST-Q and PROMIS surveys for both unilateral and bilateral reconstruction groups.

Unilateral Reconstruction—In the unilateral breast reconstruction group, autologous flap reconstruction was associated with higher PRO scores in majority of the BREAST-Q subscales compared to the implant-based group (Table 6). Patients in the autologous flap group reported significantly higher scores compared to those in the implant-based group in satisfaction with breast by 9.85 ($p<0.001$), in psychosocial well-being by 4.84 ($p=0.006$), and in sexual well-being by 11.42 ($p<0.001$). Of note, a higher percentage of patients in the implant-based reconstruction group elected to pursue contralateral breast procedures for symmetry compared to patient in the autologous group (59.5% vs. 45.1%), and this difference was controlled for in the multivariable analysis. Post-mastectomy radiotherapy negatively impacted PRO measures across the board including satisfaction with the breast, psychosocial well-being, physical well-being, and sexual well-being.

Bilateral Reconstruction—Interestingly, the superior performance of autologous flaps in terms of PROs was less pronounced in the setting of bilateral breast reconstruction. There was no significant difference between the autologous flap group and the implant-based reconstruction group in psychosocial well-being and physical well-being scores (Table 7). Although the autologous flap group demonstrated higher sexual well-being score (mean difference: 4.20, $p=0.056$) and lower PROMIS physical well-being score (mean difference: -1.21 , $p=0.060$), this did not reach a statistical significance. In the setting of bilateral reconstruction, the autologous group demonstrated significantly higher scores only for satisfaction with breast (mean difference: 5.13, $p=0.001$); however, even with this score the effect size was smaller compared to the difference noted in a unilateral reconstruction setting.

Discussion:

When considering the advantages and disadvantages of various reconstruction options, the importance of considering bilateral and unilateral reconstruction has been insufficiently analyzed in the literature. Specifically, perceived advantages of one technique over another in terms of complication rates, risk factors, and patient outcomes may only be valid in the setting of unilateral reconstruction; any previously reported differences may be lessened or eliminated altogether in the setting of bilateral reconstruction. The distinction is important given the apparent growing rate of bilateral breast reconstruction in this country. Furthermore, as an increasing number of unilateral breast cancer patients explore contralateral prophylactic mastectomy, comprehensive discussions addressing the distinctions between unilateral versus bilateral reconstruction become critical in their decision-making process.

Previous studies reported superior patient satisfaction with autologous reconstruction as compared to implant-based reconstruction; however, few studies performed separate analyses for bilateral versus unilateral reconstruction. In the Michigan Breast Reconstruction Outcome Study, Alderman *et al.* (2000) demonstrated that patients undergoing autologous tissue reconstruction reported higher general and aesthetic satisfaction than patients undergoing implant-based reconstruction, with a difference maintained for at least two years following surgery(4, 11). Hu *et al.* (2009) asserted that autologous breast reconstruction patients had stable aesthetic satisfaction long-term while implant-based reconstruction patients demonstrated decreased aesthetic satisfaction; however, the results were not analyzed separately for unilateral versus bilateral reconstruction. Yueh *et al.* (2010) concluded that autologous reconstruction resulted in a higher rate of general and aesthetic satisfaction compared to implant-based reconstruction, but in this relatively underpowered study both unilateral and bilateral breast reconstruction patients were again combined into one group for analysis(1). Recently, Liu *et al.* (2014) determined that quality of life and patient satisfaction were both higher after abdominal autologous flap reconstruction compared to implant-based reconstruction, but this study was limited to evaluation of unilateral breast reconstruction patients(2). Another important consideration is the timing of previous studies, as standards of implant-based reconstruction have evolved considerably from earlier literature. For example, 92% of the study patients analyzed by Hu *et al.* who underwent implant-based reconstruction received saline implants (8). The use of acellular

dermal matrix as an adjunct and availability of silicone gel implants have improved the overall quality of implant-based breast reconstruction.

Our current study of 2125 women represents the largest prospective study that specifically compares patient reported outcomes and complications between patients undergoing bilateral versus unilateral breast reconstruction. This study describes apparent practice trends in terms of contemporary clinical decision-making. For example, patients undergoing bilateral breast reconstruction were more likely to undergo implant-based breast reconstruction(1). The higher rate of implant-based reconstruction following bilateral mastectomy is likely due to multiple factors: patients undergoing bilateral mastectomies for contralateral prophylaxis or gene-carrying risk-reduction are often younger, with less abdominal donor tissue availability, reduced willingness to accept potential donor site morbidity due to a more active lifestyle, and less willingness to take time off for a more prolonged recovery period. Furthermore, symmetry in implant-based reconstruction may be achieved more easily through a bilateral approach given no need to match a native contralateral breast.

Our study demonstrated a higher rate of overall and major complications with autologous reconstruction as compared to implant-based reconstruction for both unilateral and bilateral breast reconstruction settings. This finding was not surprising given the additional potential for donor site complications with autologous reconstruction and the significantly longer operative time required. Bilateral autologous breast reconstruction was associated with a higher complication rate compared to unilateral autologous reconstructions due to increased donor-site morbidity. This is consistent with the findings from a recent study comparing abdominal tissue-based breast reconstruction techniques which demonstrated that bilateral reconstruction was the most significant predictor for poor abdominal physical well-being(12). Although this study reported a higher rate of reconstruction failure associated with implant-based reconstruction, this result was likely due to the study-specific definition of “failure” as total flap loss which would be expected to occur much less commonly than implant explantation resulting from infection or skin flap compromise.

Consistent with prior published studies, our results demonstrated that autologous flap breast reconstruction was associated with higher satisfaction with the breast compared to implant-based reconstruction in the setting of unilateral breast reconstruction. Patients reported significantly higher PRO scores throughout the measured scales including satisfaction with breast, psychosocial well-being, and sexual well-being. However, superiority in PRO scores following autologous flap reconstruction was much less apparent in the bilateral breast reconstruction setting versus unilateral. The autologous flap reconstruction group in the bilateral setting had higher PROs with satisfaction with the breast, but this was reduced approximately fifty percent as compared to the unilateral setting. No significant difference was observed in psychosocial well-being in the bilateral setting. Of note, although the precise clinical significance of the difference in BREAST-Q scores continues to be evaluated, a difference of 4–7 points in the BREAST-Q Reconstruction Module reflects a “moderate” clinical significance, while a difference of 8–10 points reflects a “large” clinical significance(13). The degree of score differential between reconstructive methods in unilateral and bilateral setting therefore appears clinically significant.

Decision-making with respect to breast reconstruction is complex given the many important factors that must be weighed when considering specific treatment options. While some reconstructive surgeons may universally favor one reconstruction technique over another, the option that performs best in the setting of unilateral reconstruction may not carry the same advantages when applied to bilateral reconstruction. Patient counseling highlighting the potential benefits and risks of reconstructive options is critical in the shared decision-making process for breast reconstruction and should be modified depending on whether surgery will be unilateral or bilateral. While our study results confirmed that autologous flap breast reconstruction leads to improved long-term satisfaction over implant-based reconstruction, the results also suggest significant attenuation of this advantage in the bilateral reconstruction setting.

Conclusions:

Although autologous breast reconstruction is associated with significantly higher patient reported outcomes compared to implant-based reconstruction techniques, the relative advantages appear to be less compelling in the setting of bilateral breast reconstruction. Consequently, laterality, i.e. unilateral vs. bilateral breast reconstruction, needs to be taken into account when considering the various reconstructive procedure choices.

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Table 1.

Patient Characteristics by Reconstruction Laterality and Procedure Type

Variable	Unilateral			Bilateral		
	Implant	Autologous	p	Implant	Autologous	p
No. patients	600	317		994	214	
Age	52.5 (10.3)	52.7 (8.9)	0.746	45.9 (9.7)	49.8 (8.0)	<.001
BMI	26.2 (5.3)	28.3 (5.2)	<.001	25.3 (5.3)	30.0 (5.9)	<.001
Indication for mastectomy						
Therapeutic	575 (95.8%)	309 (97.5%)	0.204	835 (84.0%)	166 (77.6%)	0.024
Prophylactic	25 (4.2%)	8 (2.5%)		159 (16.0%)	48 (22.4%)	
Mastectomy type						
Nipple sparing	70 (11.7%)	8 (2.5%)	<.001	216 (21.7%)	8 (3.7%)	<.001
Simple or modified radical	530 (88.3%)	309 (97.5%)		778 (78.3%)	206 (96.3%)	
Lymph node biopsy						
SLNB	301 (50.2%)	189 (59.6%)	<.001	474 (47.7%)	96 (44.9%)	<.001
ALND	216 (36.0%)	73 (23.0%)		276 (27.8%)	29 (13.6%)	
None	83 (13.8%)	55 (17.4%)		244 (24.5%)	89 (41.6%)	
Smoking status						
None smoker	393 (66.3%)	189 (59.6%)	0.085	674 (68.6%)	118 (55.7%)	0.001
Previous smoker	187 (31.5%)	116 (36.6%)		285 (29.0%)	88 (41.5%)	
Current smoker	13 (2.2%)	12 (3.8%)		24 (2.4%)	6 (2.8%)	
Diabetes						
Yes	26 (4.3%)	24 (7.6%)	0.040	20 (2.0%)	10 (4.7%)	0.023
No	574 (95.7%)	293 (92.4%)		974 (98.0%)	204 (95.3%)	
Radiation						
Before reconstruction	24 (4.0%)	53 (16.7%)	<.001	60 (6.0%)	37 (17.3%)	<.001
During/after reconstruction	137 (22.8%)	86 (27.1%)		192 (19.3%)	33 (15.4%)	
None	439 (73.2%)	178 (56.2%)		742 (74.6%)	144 (67.3%)	
Chemotherapy						
During/after reconstruction	210 (35.0%)	120 (37.9%)	0.392	312 (31.4%)	52 (24.3%)	0.040
Not during/after reconstruction	390 (65.0%)	197 (62.1%)		682 (68.6%)	162 (75.7%)	

Table 2. Two-Year Postoperative Complication Rates by Reconstruction Laterality and Procedure Type

	Unilateral		Bilateral		<i>I</i> <i>p</i> ¹
	Implant	Autologous	Implant	Autologous	
No. patients	600	317	994	214	
Overall complication	145 (24.2%)	147 (46.4%)	287 (28.9%)	123 (57.5%)	<.001
Major complication	105 (17.5%)	87 (27.4%)	215 (21.6%)	81 (37.9%)	<.001
Reconstructive failure	41 (6.83%)	4 (1.26%)	74 (7.44%)	4 (1.87%)	0.009

I, *p*-value is based on mixed-effects logistic regression model accounting for clustering within centers.

Table 3. Multivariable Analysis on Factors Associated with Two-Year Postoperative Complication for Unilateral Reconstruction Patients

Variable	Overall complication			Major complication			Failure ¹		
	OR	95% CI	P	OR	95% CI	P	OR	95% CI	P
Age	1.02	(1.01, 1.04)	0.003	1.02	(1.00, 1.04)	0.021	1.02	(0.98, 1.05)	0.358
BMI	1.05	(1.02, 1.08)	<0.001	1.06	(1.03, 1.09)	0.001	1.08	(1.02, 1.14)	0.009
Procedure type									
Implant	-Reference-			-Reference-			-Reference-		
Autologous	2.50	(1.66, 3.77)	<0.001	2.19	(1.39, 3.47)	0.001	0.12	(0.04, 0.36)	<.001
Mastectomy type									
Simple or modified radical	-Reference-			-Reference-			-Reference-		
Nipple sparing	1.81	(1.02, 3.20)	0.042	1.63	(0.85, 3.14)	0.142	3.36	(1.27, 8.93)	0.015
Indication for mastectomy									
Therapeutic	-Reference-			-Reference-			-Reference-		
Prophylactic	0.96	(0.38, 2.41)	0.928	1.15	(0.41, 3.18)	0.789	-	-	-
Lymph node biopsy									
None	-Reference-			-Reference-			-Reference-		
SLNB	0.78	(0.49, 1.25)	0.305	0.85	(0.49, 1.45)	0.543	0.70	(0.24, 2.08)	0.519
ALND	0.90	(0.52, 1.56)	0.704	1.02	(0.55, 1.91)	0.944	1.14	(0.38, 3.46)	0.817
Smoking status									
Non smoker	-Reference-			-Reference-			-Reference-		
Previous smoker	1.01	(0.73, 1.39)	0.955	1.04	(0.73, 1.50)	0.814	1.37	(0.68, 2.77)	0.379
Current smoker	2.77	(1.18, 6.53)	0.020	1.98	(0.78, 5.01)	0.148	6.70	(1.77, 25.31)	0.005
Diabetes									
No	-Reference-			-Reference-			-Reference-		
Yes	0.94	(0.49, 1.83)	0.863	1.17	(0.58, 2.35)	0.659	1.97	(0.63, 6.17)	0.246
Radiation									
None	-Reference-			-Reference-			-Reference-		
Before reconstruction	1.15	(0.66, 1.99)	0.621	1.12	(0.60, 2.08)	0.729	2.86	(0.76, 10.73)	0.119
During/after reconstruction	1.63	(1.06, 2.48)	0.025	1.86	(1.16, 2.97)	0.009	3.40	(1.53, 7.57)	0.003
Chemotherapy									

Variable	Overall complication			Major complication			Failure [†]		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Not during/after reconstruction		-Reference-			-Reference-			-Reference-	
During/after reconstruction	1.12	(0.78, 1.60)	0.547	1.32	(0.88, 1.97)	0.181	1.70	(0.79, 3.66)	0.176

[†]For the sake of model convergence, indication for mastectomy was not included as a predictor for the model on failure.

Table 4. Multivariable Analysis on Factors Associated with Two-Year Postoperative Complication for Bilateral Reconstruction Patients

Variable	Overall complication			Major complication			Failure		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Age	1.02	(1.01, 1.04)	0.006	1.02	(1.00, 1.04)	0.018	1.02	(1.00, 1.05)	0.099
BMI	1.05	(1.02, 1.07)	<.001	1.04	(1.02, 1.07)	0.002	1.07	(1.03, 1.12)	0.001
Procedure type									
Implant	-Reference-			-Reference-			-Reference-		
Autologous	2.13	(1.44, 3.17)	<.001	1.69	(1.11, 2.56)	0.014	0.14	(0.05, 0.45)	0.001
Mastectomy type									
Simple or modified radical	-Reference-			-Reference-			-Reference-		
Nipple sparing	1.32	(0.89, 1.95)	0.162	1.00	(0.64, 1.56)	0.996	1.26	(0.59, 2.68)	0.550
Indication for mastectomy									
Therapeutic	-Reference-			-Reference-			-Reference-		
Prophylactic	0.73	(0.45, 1.18)	0.193	0.91	(0.54, 1.54)	0.737	1.20	(0.44, 3.21)	0.723
Lymph node biopsy									
None	-Reference-			-Reference-			-Reference-		
SLNB	0.68	(0.44, 1.04)	0.072	0.87	(0.55, 1.37)	0.543	0.67	(0.28, 1.60)	0.370
ALND	0.53	(0.31, 0.90)	0.018	0.67	(0.38, 1.17)	0.156	0.79	(0.30, 2.09)	0.632
Smoking status									
Non smoker	-Reference-			-Reference-			-Reference-		
Previous smoker	1.34	(1.01, 1.77)	0.045	1.27	(0.94, 1.72)	0.125	1.15	(0.68, 1.96)	0.605
Current smoker	1.88	(0.86, 4.09)	0.114	2.14	(0.97, 4.72)	0.060	3.15	(1.03, 9.60)	0.044
Diabetes									
No	-Reference-			-Reference-			-Reference-		
Yes	1.96	(0.84, 4.55)	0.119	1.55	(0.68, 3.57)	0.300	0.95	(0.23, 3.92)	0.942
Radiation									
None	-Reference-			-Reference-			-Reference-		
Before reconstruction	1.37	(0.85, 2.20)	0.195	1.33	(0.80, 2.20)	0.274	3.11	(1.30, 7.42)	0.011
During/after reconstruction	2.40	(1.61, 3.58)	<.001	2.69	(1.78, 4.07)	<.001	3.66	(1.90, 7.04)	<.001
Chemotherapy									

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Variable	Overall complication			Major complication			Failure		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Not during/after reconstruction		-Reference-			-Reference-			-Reference-	
During/after reconstruction	1.31	(0.95, 1.81)	0.096	1.36	(0.96, 1.91)	0.079	1.59	(0.88, 2.85)	0.123

Summary of Patient-Reported Outcomes Preoperatively and Two-Year Postoperatively by Reconstruction Laterality and Procedure Type

Table 5.

PRO measure	Group	Unilateral		Bilateral		I_p^I
		Implant	Autologous	Implant	Autologous	
BREAST-Q Satisfaction with breast	Baseline	65.8 (21.7)	59.6 (21.1)	62.8 (21.0)	56.1 (18.5)	<.001
	Two years postop	61.2 (18.0)	68.3 (18.1)	66.1 (17.7)	68.9 (18.6)	
BREAST-Q Psychosocial well-being	Baseline	73.0 (17.5)	69.0 (18.3)	71.2 (17.5)	66.5 (18.1)	<.001
	Two years postop	74.6 (18.7)	76.8 (18.9)	74.5 (19.0)	73.4 (19.0)	
BREAST-Q Physical well-being chest	Baseline	80.3 (13.9)	76.6 (15.8)	80.3 (14.6)	77.1 (14.7)	0.003
	Two years postop	77.2 (13.8)	76.3 (15.4)	77.3 (14.6)	74.5 (15.4)	
BREAST-Q Sexual well-being	Baseline	58.4 (19.7)	54.0 (20.4)	59.0 (18.5)	52.9 (21.5)	<.001
	Two years postop	52.8 (20.5)	58.9 (20.6)	54.7 (21.5)	54.4 (23.0)	
PROMIS physical well-being	Baseline	53.1 (6.6)	52.5 (6.9)	53.5 (6.6)	52.4 (7.1)	0.043
	Two years postop	52.6 (6.5)	51.3 (7.3)	52.8 (6.3)	49.8 (7.6)	

I_p^I For the comparison of baseline PRO between implant and autologous groups.

Multivariable Analysis on Factors Associated with Two-Year Postoperative Patient-Reported Outcomes for Unilateral Reconstruction Patients

Table 6.

Variable	Satisfaction with Breast		Psychosocial Well-being		Physical well-being		Sexual Well-being		PROMIS Physical Well-being	
	Beta	p	Beta	p	Beta	p	Beta	p	Beta	p
Baseline outcome	0.06	0.093	0.38	<0.001	0.40	<0.001	0.32	<0.001	0.35	<0.001
Age	0.09	0.262	0.25	0.002	0.12	0.029	0.40	<0.001	-0.10	0.005
BMI	-0.41	0.006	-0.13	0.377	-0.09	0.401	-0.46	0.009	-0.35	<0.001
Contralateral procedure										
No	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
Yes	0.59	0.696	1.76	0.165	-1.12	0.282	3.50	0.047	0.04	0.947
Procedure type										
Implant	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
Autologous	9.85	<0.001	4.84	0.006	1.77	0.238	11.42	<0.001	-0.14	0.830
Mastectomy type										
Simple/modified radical	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
Nipple sparing	-1.74	0.563	0.08	0.973	2.34	0.268	-0.34	0.903	-1.92	0.121
Indication										
Therapeutic	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
Prophylactic	4.55	0.303	4.69	0.236	3.20	0.257	5.22	0.237	-0.09	0.950
Lymph node biopsy										
None	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
ALND	-3.21	0.201	-2.44	0.339	0.92	0.586	0.33	0.920	-1.63	0.099
SLNB	0.59	0.775	-2.38	0.221	0.77	0.628	-1.11	0.735	-0.10	0.892
Smoking status										
Non smoker	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
Previous smoker	-2.53	0.077	-1.83	0.225	-2.85	0.017	-2.19	0.306	-1.32	0.008
Current smoker	-1.82	0.803	-8.68	0.125	-8.79	0.135	-9.46	0.204	-6.73	0.005
Diabetes										
No	-Reference-		-Reference-		-Reference-		-Reference-		-Reference-	
Yes	-2.20	0.561	3.54	0.218	0.58	0.794	-1.38	0.686	-0.05	0.972
Radiation										

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Variable	Satisfaction with Breast		Psychosocial Well-being		Physical well-being		Sexual Well-being		PROMIS Physical Well-being	
	Beta	p	Beta	p	Beta	p	Beta	p	Beta	p
None	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Before reconstruction	0.35	0.906	-1.32	0.614	0.87	0.662	-0.95	0.755	0.60	0.522
During/after reconstruction	-7.19	0.001	-6.06	0.001	-6.03	0.000	-5.36	0.044	0.01	0.985
Chemotherapy										
Not during/after reconstruction	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
During/after reconstruction	2.03	0.243	0.15	0.919	1.08	0.407	-1.28	0.542	-1.45	0.010

Table 7. Multivariable Analysis on Factors Associated with Two-Year Postoperative Patient-Reported Outcomes for Bilateral Reconstruction Patients

Variable	Satisfaction with Breast		Psychosocial Well-being		Physical well-being		Sexual Well-being		PROMIS Physical Well-being	
	Beta	p	Beta	p	Beta	p	Beta	p	Beta	p
Baseline outcome	0.13	<.001	0.39	<.001	0.37	<.001	0.40	<.001	0.41	<.001
Age	-0.09	0.146	0.13	0.102	0.01	0.875	0.10	0.182	-0.13	<.001
BMI	-0.06	0.624	-0.06	0.664	-0.36	0.000	-0.06	0.684	-0.20	0.001
Procedure type										
Implant	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Autologous	5.13	0.001	0.91	0.573	0.57	0.659	4.20	0.056	-1.21	0.060
Mastectomy type										
Simple or modified radical	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Nipple sparing	-0.20	0.914	2.23	0.164	-0.62	0.635	5.64	0.006	-0.46	0.473
Indication										
Therapeutic	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Prophylactic	0.71	0.745	3.86	0.078	2.35	0.248	1.81	0.519	0.35	0.652
Lymph node biopsy										
None	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
ALND	-2.90	0.274	0.28	0.890	1.69	0.405	0.72	0.772	-0.66	0.405
SLNB	-2.35	0.214	1.18	0.505	1.94	0.275	0.73	0.737	0.19	0.787
Smoking status										
None smoker	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Previous smoker	-3.19	0.010	-1.90	0.175	-1.79	0.089	-2.50	0.135	-0.57	0.233
Current smoker	-7.31	0.110	-4.71	0.186	-2.52	0.403	2.23	0.679	-2.03	0.191
Diabetes										
No	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Yes	0.67	0.863	7.13	0.090	-1.92	0.523	5.25	0.217	-0.24	0.883
Radiation										
None	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-	-Reference-
Before reconstruction	-0.57	0.819	-0.31	0.874	-0.44	0.798	0.28	0.932	0.93	0.293
During/after reconstruction	-8.38	<.001	-4.50	0.018	-5.59	<.001	-4.67	0.048	-0.05	0.945

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Variable	Satisfaction with Breast		Psychosocial Well-being		Physical well-being		Sexual Well-being		PROMIS Physical Well-being	
	Beta	p	Beta	p	Beta	p	Beta	p	Beta	p
Chemotherapy										
Not during/after reconstruction	-Reference-	0.866	-Reference-	0.211	-Reference-	0.812	-Reference-	0.103	-Reference-	<.001
During/after reconstruction	-0.29		-1.86		-0.24		-2.68		-1.96	