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Complications in Postmastectomy Breast Reconstruction One-year Outcomes of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study

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Abstract

Objective—In postmastectomy reconstruction, procedure choice is heavily influenced by the relative risks of the various options. This study sought to evaluate complications in a large, multicenter patient population.

Summary of Background Data—Previous studies have reported widely varying complication rates, but have been limited by their single center designs and inadequate controlling for confounders in their analyses.

Methods—Eleven sites enrolled women undergoing first time, immediate, or delayed reconstruction following mastectomy for cancer treatment or prophylaxis. Procedures included expander/implant, latissimus dorsi (LD), pedicle transverse rectus abdominis musculocutaneous (PTRAM), free TRAM (FTRAM), and deep inferior epigastric perforator (DIEP) techniques. Data were gathered pre- and postoperatively from medical records. Separate logistic regressions were conducted for all complications and major complications (those requiring rehospitalization and/or reoperation) within 1 year. Odds ratios (ORs) were calculated for procedure type, controlling for site, demographic, and clinical variables.

Results—Complication rates for 2234 patients were analyzed. Compared with expander/implant reconstructions, LD (OR) 1.95, $P = 0.026$), PTRAM (OR 1.89, $P = 0.025$), FTRAM (OR 1.94, $P = 0.011$), and DIEP (OR 2.22, $P < 0.001$) procedures were associated with higher risks of complications. Significantly higher risks were also associated with older age, higher body mass

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index (BMI), immediate reconstruction, bilateral procedures, and radiation. For major complications, regression showed significantly greater risks for PTRAM (OR 1.86, $P = 0.044$) and DIEP (OR 1.75, $P = 0.004$), than expander/implant reconstructions. Failure rates were relatively low, ranging from 0% for PTRAM to 5.9% for expander/implant reconstructions.

Conclusion—In this multicenter analysis, procedure choice and other patient variables were significant predictors of 1-year complications in breast reconstruction. These findings should be considered in counseling patients on reconstructive options.

Keywords

breast reconstruction; complications; multicenter; outcomes

Despite the widespread acceptance of breast conservation as a primary therapy for early stage breast cancer, recent reports indicate that mastectomy rates have begun to rise. This swing of the treatment pendulum back toward mastectomy has been attributed to a number of factors, most notably the increasing numbers of patients electing contralateral prophylactic mastectomies in cases of unilateral, early stage disease.[1] Breast reconstruction following mastectomy can provide significant quality of life benefits.[2,3] Due in part to passage of the Federal Women's Health and Cancer Rights Act of 1998 and to increasing public awareness of breast reconstruction, a growing number of women are opting for reconstruction. According to a recent National Cancer Database analysis of early stage breast cancer cases, reconstruction rates increased from 11.6% to 36.4% for unilateral mastectomies and from 36.0% to 57.2% for bilateral mastectomies for the period 1998 to 2011.[3]

Although implant-based procedures remain the most commonly-used techniques for mastectomy reconstruction, the number of flap-based options has multiplied dramatically in recent years: In addition to pedicle transverse rectus abdominis musculocutaneous (TRAM), free TRAM, and latissimus dorsi (LD) flaps, patients and surgeons now have newer perforator procedures, such as deep inferior epigastric perforator (DIEP) and superficial inferior epigastric perforator (SIEA) flaps, from which to choose. With so many options available, weighing the relative risks and benefits of each operation can prove challenging. Comparing risks across procedure types is particularly difficult given the lack of large, well-designed studies that evaluate complication rates. To date, published analyses of breast reconstruction complications have been limited by a range of methodological flaws, including single surgeon/single center designs, small patient populations, and lack of control for treatment selection bias and/or confounding variables.[4–7] For mastectomy patients and their providers to make truly informed reconstructive decisions, high-quality research is needed to assess the risks of these procedures.

Using a multicenter retrospective cohort design, the current study sought to compare 1-year complication rates among the common options for postmastectomy breast reconstruction.

Methods

Funded by the National Cancer Institute in 2011, the Mastectomy Reconstruction Outcomes Consortium (MROC) is a prospective cohort study bringing together 9 academic and 2 private practices in the United States and Canada with high volumes of breast reconstruction. Study centers were chosen in order to recruit an ethnically, racially, and geographically diverse patient population. We recruited sites with established clinical and research expertise across a wide range of breast reconstruction techniques. With Institutional Review Board approval at all sites, the project recruited women undergoing first-time reconstruction following mastectomy for breast cancer treatment or prophylaxis. Patients receiving first-time immediate or delayed reconstruction were eligible for study participation. Surgical options evaluated in this analysis included single and two-staged implant-based techniques; combination LD flap/implant (LD) procedures; pedicle TRAM (PTRAM) flaps; free TRAM (FTRAM) flaps; and DIEP flaps. Other, lesser used procedures, such as SIEA flaps, were not evaluated, due to insufficient case volumes.

Demographic and clinical information was gathered preoperatively and 1 week postoperatively from participants' electronic medical records (EMRs). These data were uploaded onto the Velos eResearch System, a password secure data collection platform. Demographic variables included age, race, ethnicity, education, income, marital status, and employment status. Clinical variables included procedure type; timing (immediate vs delayed reconstruction); laterality (uni- vs bilateral procedures); body mass index (BMI); lymph node management (sentinel node or axillary lymph node dissection); radiation; chemotherapy; and smoking status. Medical comorbidities were scored using the Charlson Index, which assigns points for a variety of chronic medical conditions.[8]

One year following reconstruction, participants' EMRs were reviewed again, to update clinical information and to gather complication data. A complication was defined as an adverse postoperative, surgery-related event requiring additional treatment. Data were abstracted for each individual adverse event. Complications requiring rehospitalization or reoperation were designated as “major.” Reconstructive failures, defined as complications necessitating implant or flap removal, were also recorded.

Statistical Analysis

Patient characteristics and complication outcomes across reconstructive procedure types were analyzed using 1-way analysis of variance (ANOVA) for continuous variables and Chi-square test for categorical variables. For all the analyses, we treated the patient as the analytic unit. In order to compare complication rates across the procedure types, separate mixed-effects logistic regression models were employed for (1) any type of complication, and (2) major complications (as defined above). Each model included 4 indicators for the 5 procedure types as the primary predictors, with implant-based procedures being the reference category. Patients' demographic and clinical characteristics were included as covariates. Random intercepts were also included for treatment sites (hospitals) to account for between-hospital variability. We calculated adjusted odds ratios (ORs) with 95% confidence intervals (CIs) estimated by the model. All statistical analyses were performed with SAS 9.4 (SAS Institute, Cary, NC), and statistical significance was set at 0.05.

Results

Data from 2224 patients were included for analysis. Reconstructions included 1615 implant procedures (72.3%), 73 LD flaps (3.3%), 84 PTRAM flaps (3.8%), 97 FTRAM flaps (4.3%), and 365 DIEP flaps (16.3%). A majority of participants (92.9%) received immediate reconstruction, and about half of the cohort (50.9%) underwent bilateral procedures. The majority of patients were white (86.8%) and non-Hispanic/Latino (92.9%). The average age of this cohort was 50.1 (±10.0) years and average was BMI 26.6 (±5.6) kg/m^2. As summarized in Tables 1 and 2, bivariate analyses indicated significant differences in patient demographic and clinical characteristics across procedure types.

Complication rates across procedure types are described in Table 3. Bivariate analysis revealed significantly different risks of developing any complication ($P < 0.0001$), major complications ($P = 0.002$), and reconstructive failure ($P = 0.002$) among the reconstructive procedures. For any complication, implant-based procedures were associated with the lowest rate (24.7%), while DIEP flaps resulted in the highest (46.9%). For major complications, both implant-based and LD flap procedures had lower rates, compared with PTRAM, FTRAM, and DIEP flaps. By contrast, implant patients had a higher failure rate (5.9%) than the other 4 procedures types.

Rates and bivariate analyses for specific complications are listed by procedure type in Table 4. Among breast complications, a significant procedure difference was observed for wound infection ($P = 0.005$), and among the flap procedures for chronic fat necrosis ($P = 0.017$). Wound dehiscence ($P = 0.001$) and seroma ($P < 0.0001$) differed significantly across procedures among the donor site and systemic complications.

Results from the mixed-effects logistic regression models for any complication and for major complications are summarized in Table 5. Controlling for patient characteristics, we observed significantly higher odds of developing any complication for patients with PTRAM (OR 1.89, $P = 0.025$), FTRAM (OR 1.94, $P = 0.044$), DIEP (OR 2.22, $P < 0.0001$), and LD (OR 1.95, $P = 0.026$) flaps, compared with implant-based procedures. In addition, women undergoing PTRAM (OR 1.86, $P = 0.017$) and DIEP (OR 1.75, $P = 0.004$) flaps were significantly more likely to develop major complication, compared with implant patients.

The multivariate analyses also identified several patient level characteristics that were significant predictors of complications. For any complication, older age was associated with a higher risk among those aged 45 to 54.9 years (OR 1.68, P 0.03), 55 to 64.9 years (OR 1.96, $P = 0.009$), and 65 years and above (OR 2.30, $P = 0.007$), compared with patients under age 35 years. Women with BMIs of 30.0 to 34.9 kg/m^2 (OR 1.54, $P = 0.005$) and 35 kg/m^2 or greater (OR 2.29, $P < 0.001$) were at significantly greater risk, compared with patients with normal BMIs (between 18.5 and 25 kg/m^2). Additional risk factors for any complication included immediate reconstruction (OR 1.82, $P = 0.017$), bilateral reconstruction (OR 1.52, $P < 0.0001$), and radiation therapy during or after reconstruction (OR 1.50, $P = 0.014$). Similarly, all the aforementioned characteristics except reconstruction timing were also found to be associated with significantly greater odds of major complications. Finally, Charlson scores above 1 (OR 1.59, $P = 0.018$), and chemotherapy

during or after reconstruction (OR 1.35, $P = 0.047$) were also significant predictors for major complications.

Discussion

Previous investigators assessing complication rates for breast reconstruction have reported widely varying results. For example, overall rates recorded for implant-based reconstructions have ranged from 5.8% up to 52%.[9,10] Although such disparities could be attributable to differences in study design, lengths of follow-up, or patient populations, there may be a more fundamental reason for this variation: Despite the fact that surgeons have been performing operations for hundreds of years, there is little consensus on exactly what constitutes a surgical complication.[11] Previous attempts to define complications as “any deviation from the normal postoperative course” or a “negative outcome”[12] still leave considerable room for interpretation. Attempts to devise reporting and classification systems for tracking complications have met with only limited acceptance.[13]

Despite these challenges, accurate and systematic reporting of complication data for surgical procedures remains vitally important. Complications in breast reconstruction compromise aesthetic outcomes, lower patient satisfaction, and increase costs of care.[14] Analyses that evaluate and compare risks, while controlling for individual demographic and clinical variables, can provide an evidence-based foundation for surgical decision making. For health care providers, regulators, and payers, complication rates are key measures of quality of care. Since the 1990s, the National Surgical Quality Improvement Program (NSQIP) and other large national databases have been established to evaluate surgical outcomes. For these systems, assessment of complications is still the most common metric employed for assessing quality of care and establishing clinical benchmarks.[15] Although analysis of NSQIP and other national databases can provide useful, generalizable knowledge on complications, these sources may not have sufficient clinical detail or length of follow-up to adequately evaluate outcomes for postmastectomy breast reconstruction. Multicenter, prospective outcomes research is still required to comprehensively assess the benefits and risks of the currently available options for breast reconstruction.

The relatively high complication rates observed in the MROC population may be attributable, in part, to the study's inclusion criteria for complications. Recording all adverse postoperative events related to the reconstruction and which require additional treatment certainly contributed to the large numbers of complications observed. Relying on the more traditional approach of reporting only complications requiring reoperation would have produced more conservative estimates of risk. However, our goal with MROC is to provide consumers and clinicians with a true picture of how these operations look, feel, and perform in the real world. Despite the high complication rates in our study, the incidences of reconstructive failures were relatively low, indicating that most complications were treatable, without loss of the reconstruction. When discussing the risks of reconstruction with prospective patients, this latter point is well worth making: Although they are common in all types of reconstruction and do require additional treatment, complications rarely result in failure.

Controlling for demographic and clinical variables, all flap-based procedures were associated with significantly greater risks for total (any) complications, compared with implant techniques. For major complications, FTRAM and DIEP flaps were also associated with significantly higher risks. These differences may be attributable to the length of follow-up used this study. Although most autogenous tissue complications appear to occur relatively early in the post-operative period, implant-based procedures remain at risk for problems such as leakage and capsular contracture well beyond 1 year following reconstruction.[16] Clearly, studies with longer follow-up are needed, to avail patients, providers, and payers of more realistic estimates of the relative risks. The MROC Study is continuing to track its patient population to obtain longer term outcome data.

Among demographic variables included in the regression models, only patient age had significant effects on complications. Controlling for procedure type and other demographic and clinical variables, older patients were at significantly higher risks for any complication and for major complications. Previous studies of age effects on breast reconstruction complications have produced mixed results. A multicenter, retrospective analysis by Song et al[17] assessing outcomes of autologous reconstructions in 1809 patients concluded that complications in elderly patients were “equivalent,” compared with those of younger women. In an analysis of free flap breast reconstructions, Selber et al[18] reported no difference in complications between patients under 65 and those 65 years or older. By contrast, McCarthy et al[19] concluded that age over 65 was an independent risk factor for perioperative complications in a single-center, retrospective analysis of 1170 expander/implant reconstructions.

In our regression models, a number of clinical variables also had significant effects on complication rates. Obese patients were at significantly greater risks for both any complication and major complications. This is not a new finding: Previous investigators have noted significant associations between obesity and postoperative complications for both expander/implant reconstructions[18] and autogenous tissue techniques.[20] Our study found the greatest risks of complications in women meeting World Health Organization (WHO) criteria for Class II and Class III obesity (BMI 35 kg/m^2 and above). These results are in agreement with those of a 2013 analysis of 15,937 patients from the NSQIP database by Fisher et al.[21] Evaluating outcomes for both implant- and flap-based reconstructions, they reported that obesity was a significant predictor for complications and that risk was highest for WHO Class II and III patients.[21]

Not surprisingly, bilateral reconstructions were associated with greater risks for any complication and major complications. This information is particularly relevant to patient-provider discussions weighing the pros and cons of contralateral prophylactic mastectomies in cases of unilateral breast cancer. Timing of reconstruction (immediate vs delayed) had more mixed effects on complications: Compared with delayed reconstructions, immediate procedures were associated with a significantly higher risk for any complication. However, there was no significant effect by timing on the risk of major complications. These seeming inconsistences in the results for procedure timing seem to echo findings from previous research, where some studies have reported higher complication rates for delayed

procedures,[22] while others have not found significant differences in risk for immediate versus delayed reconstruction.[18]

Other clinical covariates were noted to have significant effects on complication rates. In our study, current smokers were at a significantly higher risk for major, but not for overall complications. Previous investigators have reported mixed results in assessing the risks of tobacco in breast reconstruction: Some have identified active smoking as a significant risk factor,[23,24] while others have not observed significant effects.[25] The small numbers of active smokers in most of these analyses may reflect reluctance by many surgeons to perform breast reconstruction in this patient population.

Interestingly, our analysis did not find significant effects by chemotherapy on complications in breast reconstruction. These findings appear to confirm results of previous studies.[23,26,27] In contrast, radiation during or following reconstruction was associated with significantly greater risks for both any and major complications in our analyses. A number of published reports have indicated that radiation following reconstruction is associated with higher complication rates, compared with nonradiated reconstructions.[28–30] However, these effects may vary by procedure type: Although radiation appears to substantially raise the risk of complications in immediate expander/implant reconstructions, the impact may be far less profound for autogenous tissue procedures.[31,32] Of note, we did not see significant effects on complications for the patient cohort receiving radiation before reconstruction. There appears to be little consensus among previous studies on complication rates for breast reconstruction in previously radiated patients.[33–35]

The MROC Study's primary strengths lie in its prospective, multicenter, multi-surgeon design, and large patient population. With 11 participating sites and 57 surgeons in both academic and community settings, MROC's findings are likely to be more generalizable than previous single center analyses. However, all studies have inherent limitations, ours included. In collecting complication data, our study relied on a retrospective cohort, not a randomized controlled trial (RCT) design. Although we controlled for a wide range of socio-demographic and clinical variables in our analyses, it is still possible that the effects of unknown confounding variables could have accounted for the observed differences in complication risks across the procedural cohorts. It is likely that an RCT design would better control for these potential unknown confounders. However, surgeons and patients tend to have strong preferences for specific procedures. During recruitment of the original MROC centers in 2008 to 2009, the possibility of an RCT design was proposed to potential sites, but was roundly rejected for this reason.

Despite inclusion of 11 academic and private practice sites in the Consortium, our study's results may not be generalizable to all patients in all settings. Finally, given the almost infinite ways in which techniques vary among surgeons, it was impossible to standardize the various surgical procedures across MROC centers and practitioners. Although our analyses controlled for site, including surgeon-specific technical variations as additional variables in our analyses was not feasible.

Conclusion

This multicenter study found significant differences in risks across breast reconstruction procedure types. Despite the high complication rates observed, adverse events rarely resulted in failure of the reconstruction, a point worth making in counseling patients considering these procedures. Finally, because breast reconstruction complications may occur well beyond the first postoperative year, longer term research is needed to fully assess these risks.

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Table 1

Demographic Characteristics of Patients by Procedure Type (N =2234)

	Procedure Type					
	Implant (DTI and TE) N = 1615 (72.3%)	**PTRAM N = 84 (3.8%)**	**Free TRAM N = 97 (4.3%)**	**DIEP N = 365 (16.3%)**	**Lat Dorsi N = 73 (3.3%)**	***P***
Age, mean (SD)	49.3 (10.3)	54.0 (8.5)	52.5 (8.6)	51.4 (8.6)	53.5 (10.0)	<0.001
Race						
White	1402 (87.7%)	70 (83.3%)	77 (80.2%)	318 (88.6%)	63 (87.5%)	0.051
Black	108 (6.8%)	5 (6.0%)	14 (14.6%)	18 (5.0%)	4 (5.6%)	
Other	88 (5.5%)	9 (10.7%)	5 (5.2%)	23 (6.4%)	5 (6.9%)	
Ethnicity						
Hispanic or Latino	97 (6.1%)	1 (1.2%)	14 (14.6%)	16 (4.4%)	4 (5.7%)	0.002
Not Hispanic or Latino	1488 (93.9%)	83 (98.8%)	82 (85.4%)	346 (95.6%)	66 (94.3%)	
Education						
High school or less	114 (7.1%)	13 (15.5%)	8 (8.3%)	73 (20.1%)	12 (16.4%)	<0.001
Some college	238 (14.8%)	15 (17.9%)	20 (20.6%)	74 (20.4%)	21 (28.8%)	
College degree	716 (44.6%)	38 (45.2%)	39 (40.2%)	151 (41.6%)	26 (35.6%)	
Master/Doctoral degree	539 (33.5%)	18 (21.4%)	30 (30.9%)	65 (17.9%)	14 (19.2%)	
Income						
Less than $50,000	224 (14.3%)	25 (30.1%)	26 (27.4%)	78 (22.0%)	23 (32.4%)	<0.001
$50,000–$99,000	462 (29.5%)	31 (37.4%)	25 (26.3%)	159 (44.9%)	28 (39.4%)	
$100,000 or more	878 (56.1%)	27 (32.5%)	44 (46.3%)	117 (33.1%)	20 (28.2%)	
Marital status						
Married or partnered	1254 (78.4%)	62 (73.8%)	73 (75.3%)	291 (79.7%)	49 (68.1%)	0.186
Not married or partnered	346 (21.6%)	22 (26.2%)	24 (24.7%)	74 (20.3%)	23 (31.9%)	
Employment status						
Full-time (including student)	907 (56.9%)	44 (53%)	62 (66.7%)	219 (60.8%)	34 (47.2%)	0.096
Part-time	224 (14.1%)	9 (10.8%)	5 (5.4%)	47 (13.1%)	12 (16.7%)	
Unemployed	463 (29.1%)	30 (36.1%)	26 (28.0%)	94 (26.1%)	26 (36.1%)	

Table 2

One-year Postoperative Complication Rate by Procedure Type

	Procedure Type					
	Implant (DTI and TE) N = 1615	**PTRAM N = 84**	**Free TRAM N = 97**	**DIEP N = 365**	**Lat Dorsi N = 73**	***P****
Any complication	399 (24.7%)	32 (38.1%)	33 (34.0%)	171 (46.9%)	28 (38.4%)	<0.001
Major complication	291 (18.0%)	25 (29.8%)	23 (23.7%)	107 (29.3%)	13 (17.8%)	0.002
Reconstructive failure	95 (5.9%)	0 (0.0%)	2 (2.1%)	6 (1.6%)	2 (2.7%)	0.002

**P* value is computed from the mixed-effects logistic regression model adjusting for sites or Fisher exact test.

Table 3

Clinical Characteristics of Patients by Procedure Type (N = 2234)

	Procedure Type					
	Implant (DTI and TE) N = 1615 (72.3%)	**PTRAM N = 84 (3.8%)**	**Free TRAM N = 97 (4.3%)**	**DIEP N = 365 (16.3%)**	**Lat Dorsi N = 73 (3.3%)**	***P***
BMI, Mean (SD)	25.8 (5.5)	28.5 (5.5)	30.4 (5.0)	28.7 (5.1)	26.0 (6.9)	<0.001
Timing						
Immediate	1581 (97.9%)	75 (89.3%)	71 (73.2%)	300 (82.2%)	49 (67.1%)	<0.001
Delayed	34 (2.1%)	9 (10.7%)	26 (26.8%)	65 (17.8%)	24 (32.9)	
Laterality						
Unilateral	670 (41.5%)	70 (83.3%)	71 (73.2%)	233 (63.8%)	58 (79.5%)	<0.001
Bilateral	945 (58.5%)	14 (16.7%)	26 (26.8%)	132 (36.2%)	15 (20.6%)	
Lymph node biopsy						
None	220 (13.6%)	28 (33.3%)	31 (32.0%)	121 (33.2%)	34 (46.6%)	<0.001
SLNB	838 (51.9%)	42 (50.0%)	52 (53.6%)	170 (46.6%)	26 (35.6%)	
ALND	557 (34.5%)	14 (16.7%)	14 (14.4%)	74 (20.3%)	13 (17.8%)	
Charlson Comorbidity Index						
≤1	1472 (91.2%)	76 (90.5%)	86 (88.7%)	310 (84.9%)	64 (87.7%)	0.010
>1	143 (8.9%)	8 (9.5%)	11 (11.3%)	55 (15.1%)	9 (12.3%)	
Smoking status						
Nonsmoker	1061 (66.5%)	52 (62.7%)	60 (61.9%)	206 (56.6%)	48 (65.8%)	0.040
Previous smoker	492 (30.8%)	30 (36.1%)	35 (36.1%)	142 (39.0%)	24 (32.9%)	
Current smoker	43 (2.7%)	1 (1.2%)	2 (2.1%)	16 (4.4%)	1 (1.4%)	
Radiation						
Before reconstruction	86 (5.3%)	26 (31.0%)	40 (41.2%)	85 (23.3%)	41 (56.2%)	<0.001
During or after reconstruction	366 (22.7%)	14 (16.7%)	1 (1.0%)	76 (20.8%)	5 (6.9%)	
None	1163 (72.0%)	44 (52.4%)	56 (57.7%)	204 (55.9%)	27 (37.0%)	
Chemotherapy						
During or after reconstruction	561 (34.7%)	20 (23.8%)	12 (12.4%)	113 (31.0%)	17 (23.3%)	<0.001
Not during or after reconstruction	1054 (65.3%)	64 (76.2%)	85 (87.6%)	252 (69.0%)	56 (76.7%)	

ALND indicates axillary lymph node dissection; SLNB, sentinel lymph node biopsy

Table 4

Breast, Donor Site, and Medical Complication Rate at 1-year Postoperation by Procedure Type

	Procedure Type					
	Implant (DTI and TE) N = 1615	**PTRAM N = 84**	**Free TRAM N = 97**	**DIEP N = 365**	**Lat Dorsi N = 73**	***P****
Breast complication						
Hematoma	56 (3.5%)	3 (3.6%)	4 (4.1%)	22 (6.0%)	3 (4.1%)	0.706
Wound dehiscence	26 (1.6%)	1 (1.2%)	1 (1.0%)	13 (3.6%)	1 (1.4%)	0.425
Wound infection	162 (10.0%)	5 (6.0%)	4 (4.1%)	14 (3.8%)	6 (8.2%)	0.005
Mastectomy skin flap necrosis	107 (6.6%)	5 (6.0%)	6 (6.2%)	28 (7.7%)	4 (5.5%)	0.916
Seroma	47 (2.9%)	2 (2.4%)	0 (0.0%)	3 (0.8%)	2 (2.7%)	0.055
Capsular contracture	13 (0.8%)	—	—	—	1 (1.4%)	0.716
Implant malposition	8 (0.5%)	—	—	—	1 (1.4%)	0.331
Implant leakage, rupture, and/or deflation	18 (1.1%)	—	—	—	0 (0.0%)	1.000
Acute partial flap necrosis	—	10 (11.9%)	5 (5.2%)	9 (2.5%)	1 (1.4%)	0.153
Total flap loss	—	1 (1.2%)	2 (2.1%)	5 (1.4%)	0 (0.0%)	0.804
Chronic fat necrosis	—	6 (7.1%)	5 (5.2%)	33 (9.0%)	0 (0.0%)	0.017
Donor site or medical complication						
Hematoma at donor site	—	0 (0.0%)	0 (0.0%)	10 (2.7%)	0 (0.0%)	0.121
Wound dehiscence at donor site	—	1 (1.2%)	3 (3.1%)	31 (8.5%)	0 (0.0%)	0.001
Wound infection at donor site	—	5 (6.0%)	2 (2.1%)	12 (3.3%)	2 (2.7%)	0.587
Donor site necrosis	—	1 (1.2%)	2 (2.1%)	19 (5.2%)	0 (0.0%)	0.065
Chronic fat necrosis of the donor site	—	2 (2.4%)	0 (0.0%)	7 (1.9%)	0 (0.0%)	0.348
Donor site seroma	—	0 (0.0%)	2 (2.1%)	19 (5.2%)	14 (19.2%)	<0.001
Abdominal wall bulge, laxity or hernia	—	4 (4.8%)	3 (3.1%)	6 (1.6%)	0 (0.0%)	0.134
Deep venous thrombosis	5 (0.3%)	0 (0.0%)	1 (1.0%)	1 (0.3%)	1 (1.4%)	0.274
Pulmonary embolus	4 (0.3%)	0 (0.0%)	2 (2.1%)	4 (1.1%)	0 (0.0%)	0.039

*P value is computed from the mixed-effects logistic regression model adjusting for sites or Fisher exact test.

Table 5

Mixed Effects Logistic Regression Model for 1-year Postoperative Any and Major Complication

Predictors	Model 1: Any Complication OR (95% CI)	*P*	Model 2: Major Complication OR, 95% CI	*P*
Age group (ref: <35)				
35–45	1.52 (0.94–2.46)	0.091	2.07 (1.10–3.89)	0.024
45–55	1.68 (1.04–2.70)	0.033	2.41 (1.30–4.49)	0.006
55–65	1.96 (1.19–3.25)	0.009	3.01 (1.58–5.75)	0.001
>65	2.30 (1.26–4.20)	0.007	2.84 (1.34–6.01)	0.007
Obesity Class * (ref: Normal)				
Underweight	0.73 (0.29–1.84)	0.508	0.79 (0.27–2.36)	0.677
Overweight	1.13 (0.88–1.45)	0.324	1.26 (0.95–1.68)	0.108
Obese I	1.54 (1.14–2.08)	0.005	1.73 (1.24–2.43)	0.001
Obese II/III	2.29 (1.58–3.32)	<0.001	2.45 (1.64–3.65)	<0.001
Procedure Type (ref: DTI and TE)				
PTRAM	1.89 (1.08–3.30)	0.025	1.86 (1.02–3.40)	0.044
FTRAM	1.94 (1.17–3.23)	0.011	1.57 (0.89–2.76)	0.120
DIEP	2.22 (1.57–3.13)	<0.001	1.75 (1.19–2.58)	0.004
Lat Dorsi	1.95 (1.08–3.51)	0.026	0.98 (0.47–2.02)	0.953
Timing (ref: Delayed)				
Immediate	1.82 (1.11– 2.99)	0.017	1.17 (0.68–2.00)	0.566
Laterality (ref: Unilateral)				
Bilateral	1.52 (1.22–1.89)	<0.001	1.60 (1.25–2.04)	<0.001
Lymph node biopsy (ref: None)				
SLNB	1.08 (0.78–1.50)	0.647	1.23 (0.84–1.79)	0.284
ALND	0.98 (0.67–1.43)	0.922	1.14 (0.75–1.75)	0.541
Charlson Comorbidity Index (ref: ≤1)				
>1	1.43 (1.03–1.99)	0.032	1.77 (1.25–2.51)	0.001
Smoking status (ref: Nonsmoker)				
Previous smoker	1.16 (0.93–1.44)	0.192	1.14 (0.89–1.45)	0.314
Current smoker	1.62 (0.92–2.85)	0.093	1.95 (1.07–3.55)	0.028
Radiation (ref: None)				
Before reconstruction	1.07 (0.76–1.51)	0.713	1.12 (0.76–1.65)	0.561
During/after reconstruction	1.58 (1.18–2.11)	0.002	1.64 (1.19–2.27)	0.003
Chemotherapy (ref: not during/after reconstruction)				
During/after reconstruction	1.00 (0.79–1.27)	0.994	1.13 (0.86–1.49)	0.362

Note: Each model also controlled for the following demographic characteristics: race (White, Black, Other), ethnicity (Hispanic/Latino vs Not), education (high school or less, some college, college degree, graduate degree), household annual income (<50k, 50–99k, ≥100k), marital status (married or partnered vs not), employment status (full-time, part-time, unemployed).

* Based on WHO classification: Underweight (BMI <18.5kg/m^2), Normal (BMI 18.5–24.9 kg/m^2), Overweight (BMI 25.0–29.9 kg/m^2), Obese I (BMI 30.0–34.9kg/m^2), Obese II/III (BMI ≥35.0kg/m^2).

ALND indicates axillary lymph node dissection; SLNB, sentinel lymph node biopsy.