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Complications and Patient-Reported Outcomes after Abdominal-Based Breast Reconstruction: Results of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study

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Abstract

Background—Abdominal flap reconstruction is the most popular form of autologous breast reconstruction. The current study compared complications and patient-reported outcomes (PROs) after pedicled transverse rectus abdominis myocutaneous (PTRAM), free TRAM (FTRAM), deep inferior epigastric perforator (DIEP), and superficial inferior epigastric artery (SIEA) flaps.

Methods—Patients having abdominal-based breast reconstruction at 11 centers were prospectively evaluated for abdominal donor-site and breast complications. PROs were measured by the BREAST-Q and PROMIS surveys. Mixed-effects regression models were used to assess the effects of procedure type on outcomes.

Results—720 patients had one-year follow-up and 587 had two-year follow-up. Two years after reconstruction, SIEA compared with DIEP flap was associated with a higher rate of donor-site complications (OR=2.7, p=0.001), however SIEA reported higher BREAST-Q abdominal physical well-being scores than DIEP at one year (mean difference: 4.72, p=0.053, on a scale from 0 to 100). This difference was not significant at two years. Abdominal physical well-being scores at two year post-operatively were lower in PTRAM group by 7.2 points (p=0.006) than DIEP and by 7.8 points (p = 0.03) than SIEA, and in FTRAM group lower by 4.9 points (p = 0.04) than DIEP. Bilateral reconstruction had significantly lower abdominal physical well-being scores compared with unilateral reconstruction.

Conclusions—While all abdominal-based flaps are viable breast reconstruction options, DIEP and SIEA flaps are associated with a higher abdominal physical well-being than PTRAM and

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FTRAM flaps. Although SIEA flaps offer the advantage of not violating the fascia, higher rates of donor-site complications may diminish patient satisfaction.

INTRODUCTION

Over 105,000 breast reconstruction procedures were performed in the United States in 2015 [1]. While implant-based reconstruction still predominates, autologous breast reconstruction has the advantage of providing superior long-term aesthetic results. For patients opting for autologous reconstruction, the abdomen is the most commonly selected donor site [1]. Options of abdominal flap breast reconstructions include pedicled transverse rectus abdominus myocutaneous (PTRAM), free transverse rectus abdominus myocutaneous (FTRAM), deep inferior epigastric perforator (DIEP), and superficial inferior epigastric artery (SIEA) flaps.

From its description in 1982 through 2012, the PTRAM was the most frequently performed abdominal-based flap [2]. In 2012, DIEP flaps surpassed TRAM flaps in popularity, according to statistics published by the American Society of Plastic Surgeons [3]. Consistent with these statistics, the Nationwide Inpatient Sample (NIS) Database demonstrated a decrease in the number of pedicled and free TRAM flaps between 2009 and 2011, whereby DIEP flaps increased over the same period [4]. Interpretation of prior studies comparing outcomes of the available abdominal flap reconstruction modalities have been limited by their retrospective designs, lack of controls for potential confounding variables, omission of patient-reported outcome measures, and single center patient populations. Head-to-head comparisons of the procedures are lacking, and many published studies have shown contradictory results.

Our study was designed to compare surgical complications and patient-reported outcomes (PROs) among the most common abdominal-based autologous breast reconstruction modalities using data from the Mastectomy Reconstruction Outcomes Consortium (MROC) Study. The MROC Study is a prospective, multi-center, cohort study comparing outcomes of various common breast reconstruction procedures. It presents a unique opportunity to address these questions, as patients were enrolled at 11 different sites, and all abdominal-based procedures were performed, including pedicled and free TRAM, DIEP, and SIEA flaps. Our study aims were: (1) to assess abdominal donor-site and breast complications, and (2) to compare PROs for these abdominal-based flap breast reconstruction procedures.

PATIENTS AND METHODS

Study Population

Patients were recruited from the Mastectomy Reconstruction Outcomes Consortium (MROC), a five-year, prospective, multicenter cohort study of mastectomy reconstruction patients funded by the National Cancer Institute. Women 18 years or older undergoing first-time, unilateral or bilateral mastectomy breast reconstruction were eligible for participation. Fifty-seven plastic surgeons from 11 centers in the USA (Michigan, New York, Illinois, Ohio, Massachusetts, Washington, D.C., Georgia and Texas) and Canada (British Columbia and Manitoba) contributed patients to the study, which began enrollment in February 2012.

Appropriate Institutional Review Board (IRB) or Research Ethics Board (REB) approval was obtained from all participating sites.

For the purpose of this analysis, we included patients who underwent first-time immediate or delayed reconstruction after mastectomy with one of the following types of breast reconstruction: pedicled or free TRAM (including muscle-sparing free TRAM), DIEP, or SIEA flap. All patients had a minimum of one-year follow-up after reconstruction. Patients undergoing prophylactic and therapeutic mastectomies were included, as were both unilateral and bilateral reconstructions. Exclusion criteria consisted of patients who had less than one year follow-up, bilateral cases with mixed reconstruction types (e.g. implant and autologous) or mixed timing of reconstruction (e.g. immediate on one side and delayed on the other).

Data Collection

Demographic and clinical characteristics of patients were collected, including age, body mass index (BMI), laterality (unilateral vs. bilateral), indication for mastectomy (therapeutic vs. prophylactic), mastectomy type (nipple-sparing vs. skin-sparing), timing of reconstruction (immediate vs. delayed), smoking status (non-smoker, previous smoker, current smoker), radiation (none, pre-mastectomy, post-mastectomy, post-reconstruction) and adjuvant chemotherapy. Patients were also asked to report whether they had diabetes regardless of insulin-dependence.

Complications were collected by trained study staff at one-year and two-years post-operatively through review of electronic medical records (EMRs). A training manual, including study protocols and answers to questions about clinical data was developed before study implementation. Using this manual, the study manager conducted initial in-person training with each coordinator and monthly conference calls with all coordinators to ensure consistency. Additionally, the study manager performed yearly on-site data audits of clinical data and ongoing database querying for data consistency.

For the purpose of this study, cumulative two-year complication data were analyzed. Abdominal donor-site complications included hematoma, wound dehiscence, wound infection, donor site necrosis, chronic fat necrosis, seroma, abdominal wall bulge/laxity/hernia, and hypertrophic or keloid scarring. Breast complications included hematoma, wound dehiscence, wound infection, mastectomy skin flap necrosis, partial or total flap loss, chronic fat necrosis, seroma, and hypertrophic or keloid scarring.

Patient-reported outcomes (PROs) were measured using the breast reconstruction modules of the BREAST-Q and the Patient-Reported Outcomes Measurement Information System (PROMIS®) survey instruments. Both instruments have been previously validated [5, 6]. The BREAST-Q breast reconstruction module specifically measures patient satisfaction with breast, psychosocial well-being, physical well-being of chest and abdomen, and sexual well-being. Answers to questions in the BREAST-Q are allotted point values, and then the scores for different questions are added together. The summed score is then converted to a scale that ranges from 0 to 100 [7]. This process of quantifying responses was performed using the Q-score software. A higher BREAST-Q score reflects higher patient satisfaction or

health-related quality of life. PROMIS® was used to assess both physical function and pain level. Both BREAST-Q and PROMIS® questionnaires were administered to patients pre-operatively to measure baseline scores, and then post-operatively at years one and two. Patients had the option of completing the questionnaires online or in paper format. Only patients who successfully completed reconstruction were included for PRO analysis.

Statistical Analysis

Patient characteristics by four procedure groups (PTRAM, FTRAM, DIEP, SIEA) were analyzed using one-way ANOVA or chi-square tests. Cumulative two-year post-operative complication rates and both one and two-year PROs were summarized by procedure type. Multivariable adjustments were done using mixed-effects regression models to further compare the outcomes of patients across procedure types. For each model, we included three of the four procedure types as the primary predictor variables, with DIEP as the reference group. Contrasts of coefficients were done to obtain other pairs-wise comparisons between procedures. Each model also controlled for relevant clinical characteristics, baseline PRO scores (for PRO models), and included random intercepts for centers (hospitals) to account for between-center variability. Baseline and post-operative PROs as well as certain covariates were missing for some patients. To account for such missing data, multiple imputations with chained equations were employed to create 10 complete imputed data sets, each of which was used to run the regression models specified above. The results were then combined using Rubin's rules [8]. Statistical analysis was performed using SAS 9.4 (SAS Institute, Cary, NC), and statistical significance was set at 0.05.

RESULTS

Patient Characteristics

A total of 720 patients had one-year follow-up data. Of these, 89 patients underwent PTRAM, 115 patients received FTRAM, 445 patients underwent DIEP, and 71 patients received SIEA flap breast reconstructions. Among this patient cohort, 587 patients completed two-year follow-up consisting of 78 PTRAM, 92 FTRAM, 355 DIEP, and 62 SIEA flap patients. Patient-reported outcome survey response rates were 78.2 % among those patients with one-year follow-up and 74.1 % among the patients with two-year follow-up.

Table 1 summarizes the clinical characteristics of the study cohorts by type of reconstruction procedure performed. There were several statistically significant demographic differences between the procedure groups. Patients undergoing PTRAM and SIEA flaps were slightly older (53.6 and 53.2 years old, respectively), compared with those who had FTRAM or DIEP flaps (52.2 and 51.1 years old, respectively). The FTRAM and SIEA groups had slightly higher average BMIs (30.7 and 30.5, respectively) than the PTRAM and DIEP patients (28.9 and 28.8, respectively). A higher percentage of patients undergoing PTRAM had unilateral reconstruction compared with all of the other groups. A greater percentage of SIEA flaps were performed in an immediate setting (91.5%) compared with PTRAM (88.8%), DIEP (84.0%), and FTRAM (76.5%). The vast majority of patients in each procedure group had skin-sparing mastectomies (PTRAM 87 (97.8%); FTRAM 112

(97.4%); DIEP 431 (96.9%); SIEA 70 (98.6%)), and a small number of patients underwent nipple-sparing mastectomy (PTRAM 2(2.2%); FTRAM 3(2.6%); DIEP 13(2.9%); SIEA 1(1.4%)). There was no significant difference across procedure groups for mastectomy type.

Donor-Site Complications at Two Years Post-Reconstruction

The overall donor-site complication rate was 27.3% at two years post-operatively. PTRAM and FTRAMs had lower rates of any donor site complication (PTRAM 18%; FTRAM 15.2%), compared with DIEP (27.9%) and SIEA (53.2%). The SIEA group had the highest rate of seroma (30.7%), wound dehiscence (27.4 %), and wound infection (14.5 %). The abdominal wall bulge/laxity/hernia rate was higher in the PTRAM group (9 %) and in the FTRAM group (5.4 %) compared to DIEP and SIEA groups. The descriptive donor-site complication results are summarized in Table 2.

Multivariable analysis showed that SIEA flap was associated with significantly higher rates of abdominal donor-site complications (OR=2.73, p=0.001) than DIEP flap (see Table 3). Although not statistically significant, the odds of donor site complications were lower in FTRAM (OR=0.52, p=0.06) and PTRAM (OR=0.63, p=0.18) recipients than in DIEP recipients, and were significantly lower in FTRAM (OR=0.23, p<0.001) and PTRAM (OR=0.19, p<0.001) recipients than in SIEA flap recipients even after adjusting for covariates. Previous as well as current smoking and diabetes were associated with significantly higher odds of abdominal donor-site complications. Age, BMI, laterality, timing of reconstruction, radiation, and adjuvant chemotherapy did not have significant effects on donor-site complications.

Breast Complications at Two Years Post-Reconstruction

The overall two-year breast complication rate was 29.6%. FTRAM flaps had lower rates of any breast complication (19.6%), compared with other abdominal flap types (PTRAM 32.1%; DIEP 31%; SIEA 33.9%). Table 2 summarizes the descriptive breast complication results. Multivariable analyses for breast complications revealed no significant differences in the rates of overall breast complications among the abdominal flap procedures. Higher BMI and active smoking were associated with significantly greater odds of any breast complication. Age, laterality, prophylactic versus therapeutic indication, delayed reconstruction, diabetes, radiation, and adjuvant chemotherapy were found to be non-significant factors for breast complications. Table 3 presents the results of the mixed-effects logistic regression analysis for two-year post-operative breast complication.

Patient-Reported Outcome Measures

The patient-reported outcome (PRO) measure scores assessed using BREAST-Q and PROMIS survey instruments are summarized in Table 4. Prior to reconstruction, patients across the four procedure groups reported similar PRO scores. Multivariable analysis (Table 5) showed SIEA flap to be associated with higher abdominal physical well-being scores compared to DIEP flap at one year post-operatively by 4.72 (p=0.05). Interestingly, however, this difference was no longer seen at two years post-operatively (0.58, p=0.83). One year after reconstruction, the FTRAM and PTRAM showed a trend towards lower means compared with DIEP flap by 4.16 (p=0.05) and by 4.01 (p=0.08), respectively (Table 5).

FTRAM and PTRAM showed significantly lower means compared with SIEA flaps by 8.88 (p=0.002) and by 8.74 (p=0.006), respectively (by contrasts of coefficients). Two years post-operatively, both FTRAM and PTRAM flaps had significantly lower abdominal physical well-being scores compared to the DIEP flap by 4.90 (p=0.037) and by 7.22 (p=0.006), respectively. Compared with SIEA flap, PTRAM also had lower scores by 7.80 (p=0.03), while FTRAM showed a trend towards lower scores by −5.48 (p=0.09). Bilateral breast reconstruction was associated with lower abdominal physical well-being scores by 3.38 (p=0.05) at one year and by 7.57 (p<0.001) at two years post-operatively (results not shown). Age, BMI, prophylactic indication, timing of reconstruction, diabetes, radiation, and adjuvant chemotherapy were not significant variables in abdominal well-being.

In contrast to the abdomen-specific PRO results, multivariable analysis of the BREAST-Q PRO scales unrelated to the abdominal donor site for the most part demonstrated no significant differences among the reconstruction procedure groups compared at both one and two years post-operatively (Table 5). However, the PTRAM group reported significantly lower physical well-being of chest scores at two years post-operatively by 3.92 (p=0.040) compared to the DIEP group. There were no significant differences in physical function or pain scores across PTRAM, FTRAM, DIEP, and SIEA flaps as measured by the PROMIS® survey instrument (Table 5).

DISCUSSION

The abdomen remains the most commonly used donor site for autologous breast reconstruction. Our current study employs data from MROC, the largest prospective multicenter database available, to compare the four most commonly performed abdominal-based flap breast reconstructions: PTRAM, FTRAM, DIEP, and SIEA flaps.

Patient Characteristics

We found some significant differences in the baseline clinical characteristics of patients in the different procedure groups. The differences in age and BMI, while statistically significant, are not that clinically significant. The higher proportion of unilateral reconstructions in patients undergoing PTRAM and bilateral reconstruction in patients undergoing DIEP flaps likely reflects surgeon preferences to minimize muscle harvest based on the number of sides to be reconstructed. SIEA flaps were performed more commonly in an immediate setting and were more likely to be irradiated after reconstruction. Most importantly, all of these differences were controlled for in the multivariable analysis.

Complications

The rate of complications after SIEA flaps was higher in our study compared to earlier benchmarks in the literature, with an overall abdominal complication rate of 53.2% at two years. This appeared to be secondary to the high rate of seroma after SIEA flap which was prospectively found to be approximately 30%. Our relatively high SIEA abdominal complication rates surpass the complication rates reported by prior studies. Chevray *et al.* reported on their early experience with SIEA flaps from consecutive patients undergoing abdominally-based free flap breast reconstruction between 2001 and 2002 and reported no

seromas [9]. More recent studies by Selber *et al.* of 69 SIEA flaps in 63 patients between 2003 and 2007 and Sarik *et al.* of 47 patients between 2008 and 2014 both found a 2.9% incidence of seroma[10, 11]. Reports of SIEA flaps are limited in the literature because these procedures are performed less commonly and most studies have focused on either hernia/bulge rates or microvascular complications [10–13]. Our relatively high rate of SIEA flap donor site complications may reflect the more rigorous and systematic prospective data collection methods utilized in our study and its ability to capture more complete complication data. Technical factors may also have contributed to our findings, including the extent of dissection along the superficial inferior epigastric pedicle, the number and location of drains placed, the use of quilting sutures, and the provision of a binder post-operatively to the patient.

When reviewing the breast-related complication rates, no significant differences were noted among the abdominal flap modalities compared. The FTRAM group showed a trend towards a significantly lower breast complication rates compared to the DIEP group. However, our study results suggest that the type of abdominal-based flap reconstruction does not have a significant impact on the overall breast complications. This finding is consistent with the results of Zhong *et al.*[14], who used propensity score analysis to compare muscle-sparing free TRAM flaps with DIEP flaps and found that flap type did not affect the rate of breast complications.

Patient-Reported Outcomes

Our study demonstrated some significant differences in PROs among the various abdominal flap breast reconstruction options when abdominal strength and symptoms were assessed using abdomen-specific BREAST-Q scale. This scale focuses on evaluation of symptoms such as difficulty sitting up or performing everyday activities due to abdominal muscle weakness. While it may not have been surprising that the SIEA flap demonstrated superior abdomen-specific BREAST-Q scores at year one, it was interesting to note that this difference was no longer seen at two years post-operatively. Pedicled and free TRAM flaps showed lower abdomen-specific BREAST-Q scores compared to DIEP flaps at year one, then demonstrated significantly lower scores compared to DIEP flaps at year two with even greater difference. The higher abdominal PROs for DIEP compared with pedicled and free TRAMs remained even after controlling for laterality. This finding is consistent with the results published by Macadam *et al.* in 2016 which showed higher BREAST-Q:Physical Well-Being Abdomen scores in their retrospective series of DIEP flaps compared to pedicled TRAM flaps [15]. Such results seem to indicate that patients' abdominal donor-site physical well-being continues to evolve over the long-term and further substantiate the importance of continued follow-up and evaluation, likely even beyond two years post-operatively. That being said, bilateral reconstruction showed the most significant negative impact on abdominal physical well-being (-7.57, $p<0.001$), and DIEP flap likely plays a more significant role in the setting of bilateral breast reconstructions. Future studies with longer follow-up and larger sample size are needed to determine the difference in PROs after the different abdominally-based reconstructions based on laterality.

One limitation in our PRO assessment using BREAST-Q scores is that the clinical meaning of BREAST-Q scores and the smallest clinically relevant differences in scores are not yet defined. Research in this area is ongoing, and while interpretative data on individual patient's score in abdominal physical well-being is unknown at this time, a 4-point decrease in this scale appears to be moderately significant. As these instruments become more widely utilized, the clinical meaning of BREAST-Q scores will undoubtedly be better defined and understood.

Our abdominal hernia/bulge rate was noted to be higher in PTRAM and FTRAM groups based on our descriptive data, and this finding is similar to other published studies suggesting lower abdominal hernia rates following DIEP flaps compared to PTRAM flaps [16–18]. However, interpretation of our current data in this regard is limited by the small sample size of any specific abdominal donor-site complication among the abdominal flap reconstruction types and relatively short follow-up. Prior studies have shown variable hernia/bulge rates following PTRAM flaps [15, 16, 19] as well as an apparent increase in the reported rate when patients were followed up to 64 months post-operatively [20]. Although the large number of plastic surgeons involved in our multi-center study may provide a more accurate "real world" measure of complications and quality of life compared to the retrospective single surgeon series which predominate in the clinical literature, it may also constitute an inherent limitation of our analysis due to lack of standardization in techniques, such as the abdominal donor-site closure. Factors including mesh placement versus primary fascial closure, the method of mesh inset, and drain locations may affect the rate of donor-site complications. Prior studies have shown that after primary fascial closure for unilateral free flap breast reconstructions, bulge/hernia rates are significantly higher for free TRAM flaps (11.8%) compared with DIEPs and muscle-sparing free TRAM flaps (4–5%), but use of mesh successfully reduced the bulge/hernia rate by 70% with no subsequent difference in bulge/hernia rates among the three flap groups [20]. Our results are also limited by the fact that patients who underwent muscle-sparing free TRAM flaps were included in the free TRAM flap group. The degree of muscle or fascia sparing in the free TRAM flap group was not specified on a case-by-case basis, and this lack of differentiation could have enhanced the free TRAM results. Additionally, prior abdominal surgery could have impacted the abdominal hernia/bulge complication rate (9), but these data were not available for our current analysis. Future prospectively designed studies would be valuable specifically comparing long-term abdominal donor-site outcomes following different donor-site closure techniques and degrees of muscle-sparing among TRAM flap techniques.

Although no procedure effect was seen in the PROs measured by the PROMIS survey, this may reflect the more generic nature of the PROMIS survey instrument and its limitation in assessment of more specific physical function such as the abdominal well-being. Nonetheless, bilateral breast reconstruction and higher BMI were consistently associated with significantly lower physical function scores at both one and two years post-operatively. These findings highlight the importance of considering other clinical factors, such as obesity and bilateral breast reconstruction, in addition to the reconstruction procedure type, as risk factors for poor long-term physical function. For instance, the decision to commit to prophylactic bilateral mastectomies with abdominal flap reconstruction should be made with caution. Similarly, women with unilateral breast cancers who desire a contralateral

prophylatic mastectomy and bilateral autologous reconstruction should be made aware of the anticipated negative impact that this decision will have on their abdominal well-being (in comparison to unilateral autologous reconstruction).

When reviewing the breast-related patient satisfaction scores, general patient and clinical factors seem to play a more significant role than the specific abdominal flap procedure type. No significant difference in breast-related PROs was noted among the abdominal flap modalities compared after controlling for other covariates. Those covariates that were found to be significant factors for breast-related PRO outcomes, such as obesity, radiotherapy, and age, have been addressed in other MROC-based publications [21–24].

CONCLUSIONS

Although all abdominally-based flaps are viable options for breast reconstruction, patient counseling should highlight data-driven differences in complication rates and PROs. Care should be taken with the abdominal donor site for SIEA flaps, where the high rate of complications such as seroma and dehiscence can diminish the positive effect of abdominal donor-site strength preservation on long-term PROs. Pedicled and free TRAM flap patients have lower abdominal physical well-being compared to DIEP flap and SIEA flap patients. Our current study results suggest that two-year follow-up may not be sufficient when trying to evaluate true outcomes of abdominal flap reconstructions and ongoing longer term follow-up is necessary to determine the ultimate impact in terms of physical function and patient satisfaction.

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Table 1

Clinical Characteristics of Patients by Procedure Type

Variable	PTRAM n=89	FTRAM n=115	DIEP n=445	SIEA n=71	p-Value
Age, mean (SD)	53.6 (8.5)	52.2 (8.6)	51.1 (8.8)	53.2 (8.2)	0.036
BMI, mean (SD)	28.9 (5.6)	30.7 (5.2)	28.8 (5.2)	30.5 (7.3)	0.002
Laterality					
Unilateral	72 (80.9%)	73 (63.5%)	257 (57.8%)	47 (66.2%)	0.001
Bilateral	17 (19.1%)	42 (36.5%)	188 (42.2%)	24 (33.8%)	
Indication					
Therapeutic	85 (95.5%)	105 (91.3%)	394 (88.5%)	65 (91.5%)	0.212
Prophylactic	4 (4.5%)	10 (8.7%)	51 (11.5%)	6 (8.5%)	
Timing of reconstruction					
Immediate	79 (88.8%)	88 (76.5%)	374 (84.0%)	65 (91.5%)	0.025
Delayed	10 (11.2%)	27 (23.5%)	71 (16.0%)	6 (8.5%)	
Smoking					
Non-smoker	53 (60.2%)	71 (61.7%)	259 (58.5%)	41 (57.7%)	0.707
Previous smoker	34 (38.6%)	42 (36.5%)	167 (37.7%)	29 (40.8%)	
Current smoker	1 (1.1%)	2 (1.7%)	17 (3.8%)	1 (1.4%)	
Diabetes	7 (7.9%)	5 (4.3%)	29 (6.5%)	8 (11.3%)	0.316
Radiation					
None	49 (55.1%)	67 (58.3%)	260 (58.4%)	34 (47.9%)	<.001
Pre-mastectomy	21 (23.6%)	24 (20.9%)	56 (12.6%)	6 (8.5%)	
Post-mastectomy	6 (6.7%)	22 (19.1%)	44 (9.9%)	5 (7.0%)	
Post-reconstruction	13 (14.6%)	2 (1.7%)	85 (19.1%)	26 (36.6%)	
Adjuvant Chemotherapy					
Yes	20 (22.5%)	13 (11.3%)	126 (28.3%)	33 (46.5%)	<.001
No	69 (77.5%)	102 (88.7%)	319 (71.7%)	38 (53.5%)	

Table 2

Two Year Postoperative Complication Rate by Procedure Type

Complication	Total n=587	PTRAM n=78	FTRAM n=92	DIEP n=355	SIEA n=62
Donor site complication					
Any donor site complication	160 (27.3%)	14 (18%)	14 (15.2%)	99 (27.9%)	33 (53.2%)
Hematoma	12 (2%)	0 (0%)	0 (0%)	8 (2.3%)	4 (6.5%)
Wound dehiscence	59 (10.1%)	2 (2.6%)	3 (3.3%)	37 (10.4%)	17 (27.4%)
Wound infection	28 (4.8%)	6 (7.7%)	3 (3.3%)	10 (2.8%)	9 (14.5%)
Donor site necrosis	34 (5.8%)	2 (2.6%)	2 (2.2%)	25 (7%)	5 (8.1%)
Chronic fat necrosis	16 (2.7%)	1 (1.3%)	1 (1.1%)	12 (3.4%)	2 (3.2%)
Seroma	49 (8.3%)	2 (2.6%)	3 (3.3%)	25 (7%)	19 (30.7%)
Abdominal wall bulge, laxity or hernia	18 (3.1%)	7 (9%)	5 (5.4%)	6 (1.7%)	0 (0%)
Hypertrophic or keloid scarring	7 (1.2%)	1 (1.3%)	1 (1.1%)	5 (1.4%)	0 (0%)
Breast complication					
Any breast complication	174 (29.6%)	25 (32.1%)	18 (19.6%)	110 (31%)	21 (33.9%)
Hematoma	40 (6.8%)	3 (3.9%)	5 (5.4%)	25 (7%)	7 (11.3%)
Wound dehiscence	32 (5.5%)	2 (2.6%)	3 (3.3%)	23 (6.5%)	4 (6.5%)
Wound infection	34 (5.8%)	7 (9%)	4 (4.4%)	22 (6.2%)	1 (1.6%)
Mastectomy skin flap necrosis	49 (8.3%)	6 (7.7%)	6 (6.5%)	31 (8.7%)	6 (9.7%)
Partial flap necrosis	20 (3.4%)	9 (11.5%)	3 (3.3%)	8 (2.3%)	0 (0%)
Total flap loss	7 (1.2%)	1 (1.3%)	2 (2.2%)	4 (1.1%)	0 (0%)
Chronic fat necrosis	55 (9.4%)	8 (10.3%)	6 (6.5%)	34 (9.6%)	7 (11.3%)
Hypertrophic or keloid scarring	9 (1.5%)	0 (0%)	0 (0%)	8 (2.3%)	1 (1.6%)
Seroma	7 (1.2%)	2 (2.6%)	0 (0%)	4 (1.1%)	1 (1.6%)

Table 3

Mixed-Effects Logistic Regression Model for Two Years Postoperative Complication

Variable	Any donor site complication			Any breast complication		
	OR	**95% CI**	***p***	**OR**	**95% CI**	***p***
Age	1.01	(0.99, 1.03)	0.480	1.01	(0.99, 1.04)	0.205
BMI	1.03	(0.99, 1.07)	0.131	1.08	(1.04, 1.12)	<.001
Procedure type						
DIEP		-Ref-			-Ref-	
PTRAM	0.63	(0.32, 1.24)	0.178	0.94	(0.46, 1.94)	0.872
FTRAM	0.52	(0.27, 1.02)	0.057	0.51	(0.25, 1.02)	0.058
SIEA	2.73	(1.51, 4.96)	0.001	1.15	(0.61, 2.17)	0.668
Bilateral reconstruction	1.11	(0.71, 1.73)	0.645	1.21	(0.79, 1.87)	0.384
Prophylactic mastectomy	1.73	(0.86, 3.47)	0.125	1.45	(0.71, 2.94)	0.304
Delayed reconstruction	0.35	(0.11, 1.09)	0.069	0.48	(0.18, 1.30)	0.151
Smoking						
Non-smoker		-Ref-			-Ref-	
Previous smoker	1.59	(1.06, 2.39)	0.024	1.07	(0.72, 1.60)	0.721
Current smoker	3.94	(1.44, 10.81)	0.008	3.14	(1.13, 8.68)	0.028
Diabetes	2.36	(1.15, 4.88)	0.020	0.94	(0.44, 1.97)	0.860
Radiation						
None		-Ref-			-Ref-	
Before mastectomy	0.73	(0.39, 1.37)	0.324	1.63	(0.93, 2.89)	0.090
After mastectomy before reconstruction	1.41	(0.39, 5.11)	0.602	1.73	(0.58, 5.16)	0.325
After reconstruction	1.15	(0.65, 2.06)	0.629	1.00	(0.55, 1.84)	0.996
Adjuvant chemotherapy	0.97	(0.58, 1.63)	0.912	1.13	0.68, 1.88)	0.647

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Table 4

Summary of Unadjusted Patient-reported Outcome (PRO) Scores

PRO	Assessment time	PTRAM	FTRAM	DIEP	SIEA	p-value[1]
BREAST-Q: Satisfaction with breast	Pre-op	55 (22.5)	50.7 (21.6)	55.1 (21.6)	54.1 (19.5)	0.283
	One year post-op	69.6 (15.8)	67.8 (20.4)	67.9 (17.1)	65.1 (17.9)	
	Two years post-op	71.2 (16.2)	68.9 (18.4)	67.4 (19.1)	66.8 (18.1)	
BREAST-Q: Psychosocial well-being	Pre-op	66 (19.3)	66.2 (20.5)	65.6 (18.1)	62.4 (17.3)	0.530
	One year post-op	76.8 (19)	73.9 (22.8)	74.4 (18.6)	72.2 (18.8)	
	Two years post-op	77.7 (20.1)	77.4 (19.5)	74.8 (19)	74.6 (17.8)	
BREAST-Q: Physical well-being (chest and upper body)	Pre-op	79.1 (14.3)	77.5 (15.5)	75.7 (15.1)	74.1 (17.1)	0.110
	One year post-op	78.2 (15.1)	75.2 (16.4)	74.1 (14.4)	75.8 (15.8)	
	Two years post-op	75 (13.3)	76.2 (17.3)	75.7 (14.5)	74.1 (18.2)	
BREAST-Q: Physical well-being (abdomen)	Pre-op	87.3 (15.6)	86.6 (16.4)	87 (15.3)	87.6 (15.1)	0.976
	One year post-op	72.5 (18.2)	71.7 (21.7)	75.3 (18.5)	79.6 (18.2)	
	Two years post-op	72.2 (19.8)	73.3 (22.2)	78.1 (19.1)	78.3 (18.7)	
BREAST-Q: Sexual well-being	Pre-op	48.2 (23.4)	46.5 (22.9)	50.9 (21.7)	50.5 (21.4)	0.268
	One year post-op	56.6 (19.8)	54.7 (23.1)	55.8 (20.7)	52.7 (20.6)	
	Two years post-op	54.4 (22.8)	58.9 (23.4)	56.1 (21.2)	58 (23.4)	
PROMIS: Physical function	Pre-op	51.7 (7.7)	52.7 (6.6)	52 (7.1)	50.2 (7.9)	0.140
	One year post-op	50.1 (7.5)	50.6 (7.6)	50.2 (7.2)	49.3 (7.4)	
	Two years post-op	51.7 (7.1)	51.5 (7.4)	50.6 (7.4)	49.1 (8)	
PROMIS: Pain interference	Pre-op	46.1 (7.8)	46.2 (7.9)	47.1 (7.8)	48 (8.7)	0.319
	One year post-op	47.5 (8.6)	47.4 (8.8)	48.4 (8.2)	48.9 (8.3)	
	Two years post-op	47 (8.1)	46.7 (8.4)	48.3 (8.6)	49.8 (9.6)	

Note: cell values are mean (SD).

[1]For the comparison of baseline PROs across procedure types.

Table 5

Adjusted Mean Difference between Procedure Types (with DIEP as Reference Category) on BREAST-Q and PROMIS

PRO	Procedure	One year post-op		Two years post-op	
		Adjusted mean difference[1] (95% CI)	*P*	Adjusted mean difference[1] (95% CI)	*P*
BREAST-Q: Satisfaction with breast	DIEP	-Ref-		-Ref-	
	PTRAM	1.36 (−3.45, 6.17)	0.577	2.67 (−2.53, 7.87)	0.313
	FTRAM	0.04 (−4.56, 4.63)	0.987	2.12 (−2.90, 7.14)	0.406
	SIEA	−1.82 (−6.37, 2.72)	0.431	0.42 (−5.56, 6.40)	0.889
BREAST-Q: Psychosocial well-being	DIEP	-Ref-		-Ref-	
	PTRAM	1.27 (−3.43, 5.97)	0.595	0.62 (−3.95, 5.20)	0.789
	FTRAM	−1.14 (−5.33, 3.05)	0.593	−0.08 (−5.33, 5.18)	0.977
	SIEA	−0.67 (−5.66, 4.32)	0.791	1.64 (−3.64, 6.91)	0.541
BREAST-Q: Physical well-being (chest and upper body)	DIEP	-Ref-		-Ref-	
	PTRAM	1.52 (−1.94, 4.99)	0.388	−3.92 (−7.66, −0.18)	0.040
	FTRAM	−1.55 (−5.35, 2.24)	0.417	−2.22 (−5.89, 1.45)	0.234
	SIEA	3.42 (−0.22, 7.05)	0.065	0.76 (−3.44, 4.95)	0.722
BREAST-Q: Physical well-being (abdomen)	DIEP	-Ref-		-Ref-	
	PTRAM	−4.01 (−8.48, 0.45)	0.078	−7.22 (−12.30, −2.14)	0.006
	FTRAM	−4.16 (−8.33, 0.02)	0.051	−4.90 (−9.50, −0.31)	0.037
	SIEA	4.72 (−0.07, 9.52)	0.053	0.58 (−4.79, 5.95)	0.832
BREAST-Q: Sexual well-being	DIEP	-Ref-		-Ref-	
	PTRAM	0.81 (−4.31, 5.93)	0.755	−2.61 (−8.97, 3.75)	0.416
	FTRAM	−2.33 (−7.10, 2.44)	0.335	2.35 (−3.40, 8.10)	0.420
	SIEA	−2.66 (−8.63, 3.31)	0.378	1.97 (−4.15, 8.09)	0.526
PROMIS: Physical function	DIEP	-Ref-		-Ref-	
	PTRAM	0.00 (−2.09, 2.10)	0.996	1.48 (−0.59, 3.55)	0.159
	FTRAM	−0.03 (−2.36, 2.30)	0.980	0.42 (−1.52, 2.36)	0.666
	SIEA	1.26 (−0.74, 3.26)	0.212	1.20 (−1.09, 3.49)	0.302

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PRO	Procedure	One year post-op		Two years post-op	
		Adjusted mean difference[1] (95% CI)	*P*	Adjusted mean difference[1] (95% CI)	*P*
PROMIS: Pain	DIEP	-Ref-		-Ref-	
	PTRAM	−0.07 (−2.10, 1.97)	0.949	0.44 (−2.25, 3.13)	0.745
	FTRAM	0.34 (−1.91, 2.60)	0.761	−0.50 (−2.57, 1.57)	0.636
	SIEA	−0.60 (−2.54, 1.34)	0.544	0.11 (−2.34, 2.57)	0.928

[1] Denotes the mean difference in PRO between the corresponding procedure type and DIEP (reference category); Based on separate mixed-effects regression model for each PRO outcome. Each model included as covariates baseline outcome, age, BMI, laterality, indication for mastectomy, timing of reconstruction, smoking status, diabetes, radiation and chemotherapy; Each model also included random intercepts for centers (hospitals) to account for between-center variability. The results were combined based on 10 multiply imputed data sets.