

Complications in Postmastectomy Breast Reconstruction: Two-Year Results of the Michigan Breast Reconstruction Outcome Study

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In this study, the effects of procedure type, timing, and other clinical variables on complication rates in mastectomy reconstruction were prospectively evaluated. Using a prospective cohort design, women undergoing first-time, immediate or delayed breast reconstruction were recruited from 12 centers and 23 plastic surgeons. Complication data for expander/implant, pedicle transverse rectus abdominis musculocutaneous (TRAM) flap, and free TRAM flap procedures were evaluated 2 years after surgery in 326 patients. For each patient, the total number of complications was recorded and the complication data were dichotomized in two ways: (1) total complications and (2) major complications (those requiring reoperation, rehospitalization, or nonperioperative intravenous antibiotic treatment). The effects of procedure type, timing, radiotherapy, chemotherapy, age, smoking, and body mass index on complication rates were analyzed using logistic regression. Immediate reconstructions had significantly higher total as well as major complication rates, compared with delayed procedures ($p = 0.011$ and 0.005 , respectively). Furthermore, higher body mass indexes were associated with significantly higher total and major complication rates ($p = 0.005$ and $p < 0.001$, respectively). No significant effects on complication rates were noted for procedure type or for the other independent variables, although there was evidence of trends for higher total and major complication rates in implant patients who received radiotherapy and a trend for higher major complication rates in TRAM flap patients who received chemotherapy. It was concluded that (1) immediate reconstructions were associated with significantly higher complication rates than delayed procedures, and (2) procedure type had no significant effect on complication rates. (*Plast. Reconstr. Surg.* 109: 2265, 2002.)

Previous studies have demonstrated significant psychosocial and health-status benefits for

breast reconstruction after mastectomy. Breast reconstruction promotes a sense of wellness and reverses many of the psychological and emotional sequelae associated with mastectomy.¹⁻³ Although reconstruction offers considerable benefits for recovering breast cancer patients, a variety of risks have been described for these procedures. The surgical literature is replete with studies reporting complication rates for a wide range of reconstructive techniques. However, the generalizability and validity of previous reports have been hampered by a number of methodologic flaws, including small patient populations drawn from single centers, retrospective study designs, absence of comparison groups, incomplete patient follow-up, and failure to control for potential confounding variables.⁴⁻⁷

The availability of reliable outcome data is becoming increasingly important in the current health-care environment. Research identifying the risks and benefits of medical interventions impacts health policy across a range of issues, including patient-provider decision making, evidence-based medicine, patient safety, and health-care quality improvement. Patients, providers, and payers rely on risk-benefit data in choosing treatment options. This is particularly true in postmastectomy breast reconstruction, for which a variety of choices are available, involving both timing (immediate versus delayed reconstruction)

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and type (implant versus autogenous-tissue techniques) of surgical procedures. Knowledge about the risks of reconstruction is not only essential to choosing the "right" operation for each woman but is also a necessary prerequisite for the documentation of informed patient consent. Finally, reliable data on complications can serve as a basis for promoting patient safety and quality improvement by identifying practices associated with higher (or lower) complication rates.

The purpose of our study was to describe and compare complication rates associated with three common types of postmastectomy breast reconstruction: expander/implant, pedicle transverse rectus abdominis musculocutaneous (TRAM) flap, and free TRAM flap techniques. To enrich the applicability of the study, we also evaluated the effects of procedure timing on complication rates, comparing immediate reconstructions (those performed at the time of the mastectomy) with delayed procedures. Furthermore, we evaluated the effects of other variables that might be associated with patient outcomes, such as smoking status, body mass index, patient age, chemotherapy, and radiotherapy.

PATIENTS AND METHODS

Study Population

Patients were recruited as part of the Michigan Breast Reconstruction Outcome Study, a prospective, multicenter cohort study of mastectomy reconstruction patients. Women undergoing first-time, immediate or delayed reconstructions with expander/implant, pedicle TRAM flap, or free TRAM flap techniques were eligible for participation. Both unilateral and bilateral procedures were included. Twenty-three plastic surgeons from 12 centers in Michigan, Pennsylvania, Louisiana, and Ontario contributed patients to the study from 1994 to 1998.

Data Collection

Two years after reconstruction, complication data were collected from hospital and office records and patient telephone interviews. A complication was defined as an adverse postoperative event occurring as a direct consequence of reconstruction and requiring additional treatment beyond that normally associated with the reconstruction. Thus a small suture sinus that required removal of a suture in an

office setting would not be considered a complication. By contrast, cellulitis treated with outpatient oral antibiotics or delayed wound healing that required dressing changes would be designated as complications under the study protocol. A complication was considered major if the patient required reoperation, rehospitalization, or nonperioperative intravenous antibiotic treatment.

Data Analysis

For each patient, the numbers of total complications and major complications directly related to the reconstruction were obtained. From these, two dichotomous (yes/no) variables were created, indicating the presence of (1) at least one complication, referenced as total complications, and (2) at least one major complication. The analyses described below were performed separately, with the response variables being total complications and major complications. For each response variable, complication rates were compared between timings of reconstruction (immediate versus delayed techniques), using chi-square tests. Similarly, complication rates were compared between procedure types (expanders/implants versus TRAM flaps and pedicle TRAM versus free TRAM flaps), using chi-square tests.

To adjust for possible confounding variables, logistic regression analyses were performed using total complications and major complications as response variables. The primary independent variables of interests were procedure type and procedure timing. For the three procedure types, two dummy variables were created to indicate the pedicle and free TRAM flap groups. The dummy variables assessed the effect of the particular procedure type on complication rates relative to the expander/implant group. The models also included the independent variables that were thought to be associated with complications, including body mass index, patient age, radiotherapy before and after surgery, chemotherapy, and smoking status. Body mass index and age were set as continuous variables, and the others were used as dummy variables. Smoking status was assessed using a dichotomous variable (yes/no) reflecting the patient's current smoking status.

As a measure of association, adjusted odds ratios and their 95 percent confidence intervals were calculated for each of the independent variables, using coefficients and their standard errors estimated from the logistic re-

gression model. For a continuous independent variable, the odds ratio measures the relative change in the odds of a complication for a one-unit increase in the independent variable. For example, when the other independent variables are controlled for, an adjusted odds ratio of 1.13 for body mass index suggests that every one-unit increase in body mass index is associated with a 13 percent increase in the risk of having at least one complication. In the case of a dummy independent variable, such as procedure type or timing, the odds ratio measures the odds of a complication relative to the reference category. For example, when the other independent variables are controlled for, an adjusted odds ratio of 2.0 for immediate reconstruction would suggest that patients who undergo immediate reconstructions are twice as likely to have at least one complication than are those who undergo delayed procedures. For all analyses, statistical significance was set at the level of 0.05.

In our preliminary analyses, we found no significant differences in complication rates by laterality. Therefore, the data for unilateral and bilateral reconstructions were combined in subsequent analyses. When we reconsidered laterality in our final model, we also did not find significant differences in the relationship between complication rates and other predic-

tors by laterality, and thus the results reported in this article are from the combined data.

RESULTS

Of the 460 patients enrolled in the study, 64 patients withdrew, yielding a dropout rate of 14 percent. Of the remaining 396 patients, complication data at the time of the analysis were available for 344 women at 2 years after surgery. After excluding those patients who underwent combined immediate and delayed bilateral reconstructions, complete data from 326 patients were available for the analyses. Table I summarizes the demographic characteristics of the study population, and Table II displays the distribution of procedure types and timings. Of the three types of procedures, pedicle TRAM flaps comprised the largest cohort, and there were approximately twice as many immediate reconstructions, compared with delayed procedures. The distribution of procedure types varied among immediate and delayed reconstructions ($p < 0.01$, chi-square test); the majority of delayed reconstructions involved pedicle TRAM flaps. No significant differences were observed across procedure types with regard to (1) patient demographics such as marital status, education, race, income, employment status, (2) insurance payer, or (3) comorbidities.

TABLE I
Demographic Characteristics of the Study Population*

Characteristic	Implants		Pedicle TRAM Flaps		Free TRAM Flaps	
	No.	%	No.	%	No.	%
Age, mean (years)	47.9		49.2		46.2	
Race						
Caucasian	69	87.3	150	83.8	60	89.5
African American	4	5.1	13	7.3	2	3.0
Asian	0		2	1.0	2	3.0
Hispanic	1	1.3	1	0.6	1	1.5
Native American	0		1	0.6	1	1.5
Other/missing	5	6.3	12	6.7	1	1.5
Education						
< High school	2	2.5	6	3.4	2	3.0
High school	18	22.8	28	15.6	17	25.4
College	44	55.7	100	55.9	41	61.2
Graduate	24	30.4	54	30.2	16	23.9
Missing	3	3.8	2	1.1	0	
Income						
< 15,000	3	3.8	2	1.1	4	6.0
15,000–24,999	7	8.9	14	7.8	5	7.5
25,000–49,999	27	34.2	38	21.2	20	30.0
50,000–75,000	16	20.3	62	34.6	24	35.8
> 75,000	31	39.2	66	36.9	22	32.8
Missing	7	8.9	8	4.5	2	3.0

TRAM, transverse rectus abdominis musculocutaneous.

* Does not include one patient who received both a free and a pedicle TRAM flap.

TABLE II
Distribution of Procedure Types and Timing*

Procedure Timing	Implants		Pedicle TRAM Flaps		Free TRAM Flaps		Total
	No.	%	No.	%	No.	%	
Immediate	65	82.3	96	53.6	48	71.6	209
Delayed	14	17.7	83	46.4	19	28.4	116
Total	79	100.0	179	100.0	67	100.0	325

* Does not include one patient who received both a free and a pedicle TRAM flap.

Table III lists the specific types of complications by procedure type. Compared with pedicle or free TRAM flap reconstructions, patients with expander/implant reconstructions were more commonly diagnosed with wound infections. By contrast, TRAM flap procedures were associated with higher rates of cardiac and pulmonary complications than were implant techniques. Furthermore, partial flap necrosis and wound dehiscence were reported more frequently in pedicle than in free TRAM flap procedures. Of the 326 patients, 178 had no complications (54.6 percent), 95 had one complication (29.1 percent), and 53 had two to four complications (16.3 percent). In terms of major complications, 223 patients were free of major complications (68.4 percent), 77 had one major complication (23.6 percent), and 26 had two to three major complications (8.0 percent).

The risk of a postoperative complication from smoking is seen in Table IV, which shows the association of smoking with complication rates for both total and major complication groups. No associations between complication rates and the smoking variables were found (p

= 0.28 for total complications and $p = 0.87$ for major complications).

Total complication rates between the expander/implant reconstruction group and the combined TRAM flap group (both pedicle and free TRAM flaps) showed no significant difference in either the immediate or the delayed reconstructions (Table V). However, higher total complication rates were found with immediate than with delayed reconstructions for both the TRAM flap and expander/implant groups. In the TRAM flap cohort, the difference was highly significant, with a total complication rate of 52 percent for immediate versus 32 percent for delayed reconstructions ($p = 0.002$). Although the difference was not statistically significant, immediate reconstructions had a higher total complication rate (52 percent) than those delayed in the expander/implant group (36 percent). When the procedure types were combined, immediate reconstructions had a significantly higher total complication rate than did delayed procedures ($p < 0.001$).

Between the TRAM flap groups, free TRAM flaps tended to have higher total complication

TABLE III
Frequency of Complications, by Type of Reconstruction

Complication	Implants		Pedicle TRAM Flaps		Free TRAM Flaps	
	No.	%	No.	%	No.	%
Back pain	1	1.3	4	2.2	4	6.0
Hernia/abdominal wall laxity	—	—	14	7.8	8	11.9
Lymphedema	3	3.8	10	5.6	3	4.5
Capsular contracture	12	15.2	—	—	—	—
Implant shift	1	1.3	—	—	—	—
Wound dehiscence	3	3.8	10	5.6	1	1.5
Partial flap loss (fat necrosis)	5	6.3	29	16.2	10	14.9
Total flap loss	0	—	2	1.1	1	1.5
Anastomotic thrombosis	—	—	—	—	4	6.0
Implant failure	3	3.8	—	—	—	—
Infection	28	35.4	21	11.7	12	17.9
<i>Clostridium difficile</i> colitis	0	—	1	0.5	0	—
Hematoma/seroma of the breast	4	5.1	7	3.9	6	9.0
Hematoma/seroma of the abdomen	—	—	7	3.9	3	4.5
Abdominal wall necrosis	—	—	3	1.7	0	—
Cardiac/pulmonary complications	1	1.3	6	3.4	6	9.0

TABLE IV
Incidence of Postoperative Complications, by Smoking Status*

Complications	Smokers		Nonsmokers		<i>p</i>
	No.	%	No.	%	
Total complications	11 of 30	37	137 of 292	47	0.28
Major complications	10 of 30	33	93 of 292	32	0.87

* Smoking data are missing for four patients.

rates than did pedicle TRAM flaps in both the immediate (60 percent versus 49 percent, respectively) and delayed (37 percent versus 31 percent, respectively) reconstruction groups, but the differences were not statistically significant (Table VI). For both types of TRAM flap procedures, immediate reconstructions had higher total complication rates than did delayed reconstructions, with a difference of 60 percent versus 37 percent for the free TRAM flap group ($p = 0.081$) and 49 percent versus 31 percent for the pedicle TRAM flap group ($p = 0.017$). For the combined TRAM flap types, immediate reconstructions had significantly higher total complication rates than did delayed reconstructions ($p < 0.001$).

A logistic regression model was used to assess the effects of reconstruction type and procedure timing while controlling for patient age, body mass index, current smoking status, chemotherapy, and radiotherapy (both before and after surgery) (Table VII). When the other independent variables were controlled for, immediate reconstructions had an associated odds ratio of 2.16, suggesting that patients who underwent immediate reconstructions were approximately twice as likely to have had at least one complication than were those who underwent delayed procedures ($p = 0.011$). Increasing body mass index was also significantly associated with higher total complication rates, with an odds ratio of 1.08 ($p = 0.005$). Although it was not statistically significant, radiotherapy both before and after surgery had a positive association with having at least one complication (odds ratio = 1.66 and 2.00, re-

spectively). When pre- and postoperative radiotherapy populations were combined into a single variable, its associated odds ratio was 1.76 ($p = 0.057$; result not shown). Other independent variables, including procedure type, patient age, chemotherapy, and smoking status, did not show significant associations with total complication rates.

Comparing major complication rates (Table VIII) between expander/implant and TRAM flap reconstructions showed results similar to the analysis of total complication rates. No statistically significant difference was seen by procedure type for either the immediate or delayed groups. However, immediate procedures had higher major complication rates, compared with delayed procedures. For TRAM flap patients, the major complication rates were 36 percent in the immediate group and 18 percent in the delayed group ($p = 0.002$). Among expander/implant patients, major complications rates were also higher (although not statistically significant) in the immediate group (46 percent), compared with the delayed group (21 percent; $p = 0.089$). When the expander/implant and TRAM flap groups were combined, immediate reconstructions had significantly higher major complication rates than did delayed reconstructions (39 percent versus 18 percent, respectively; $p < 0.001$).

With immediate reconstructions (Table IX), free TRAM flap patients had higher major complication rates than did pedicle TRAM flap patients (46 percent versus 31 percent, respectively), although the difference was not statistically significant ($p = 0.086$). In the delayed

TABLE V
Incidence of Total Complications in Expander/Implant and TRAM Flap Procedures

Timing of Complication	Implants		TRAM Flaps		Combined		<i>p</i> *
	No.	%	No.	%	No.	%	
Immediate	34 of 65	52	76 of 145 [†]	52	110 of 210	52	0.989
Delayed	5 of 14	36	33 of 102	32	38 of 116	33	0.802
<i>p</i> *	0.260		0.002		<0.001		

* Values are from chi-square tests.

[†] Includes one patient who received a free TRAM flap on one side and a pedicle TRAM flap on the other.

TABLE VI
Incidence of Total Complications for Pedicle and Free TRAM Flap Procedures

Timing of Complication	Pedicle TRAM Flaps		Free TRAM Flaps		Combined		<i>p</i> *
	No.	%	No.	%	No.	%	
Immediate	47 of 96	49	29 of 48	60	76 of 144	53	0.194
Delayed	26 of 83	31	7 of 19	37	33 of 102	32	0.643
<i>p</i> *	0.017		0.081		<0.001		

* Values are from chi-square tests.

group, no difference in major complication rates between the two TRAM flap groups was seen ($p = 0.814$). When procedure timing was evaluated, patients who underwent immediate reconstructions had significantly higher major complication rates than did those who underwent delayed procedures. This difference was statistically significant among pedicle TRAM flap, free TRAM flap, and pedicle and free TRAM flap patients combined ($p = 0.043$, 0.022 , and 0.002 , respectively).

Logistic regression analysis of major complication rates (Table X) provided results similar to those found in the total complication rate analysis. Patients who underwent immediate reconstructions were 2.7 times more likely to have experienced a major complication, compared with those who underwent delayed procedures ($p = 0.005$). Furthermore, body mass index was positively associated with major complication rates, with an odds ratio of 1.12 ($p < 0.001$). The remaining independent variables did not have significant effects on rates of major complications.

Although they were not statistically significant, similar trends of greater risk of a complication were seen in the free TRAM flap group, relative to pedicle TRAM flap group, in both logistic regression models, including total complications as well as major complications, after other variables were controlled for. For total complications, the odds ratios were 1.50 for free TRAM flap procedures and 0.90 for pedicle TRAM flap procedures, providing an odds ratio of 1.66 ($p = 0.117$) for free TRAM flap relative to pedicle TRAM flap procedures (calculated using the linear combinations of the coefficients from the logistic regression model). Similarly, for major complications, the odds ratios were 1.02 for free TRAM flap and 0.57 for pedicle TRAM flap procedures, providing an odds ratio of 1.80 for free TRAM flap relative to pedicle TRAM flap procedures ($p = 0.09$).

When separate regression models were con-

structed for both expander/implant and TRAM flap procedures (both free and pedicle) to evaluate the significance of the independent variables, a trend of higher complications involving radiotherapy and chemotherapy was discovered. In these models, the combined effect of radiotherapy before and after surgery on expander/implant patients approached significance for both total and major complication rates ($p = 0.08$ and $p = 0.07$, respectively). Chemotherapy was associated with significantly higher major complications in TRAM flap procedures ($p = 0.03$).

DISCUSSION

In a previous report, we detailed significant gains in quality of life and psychosocial well-being among women who underwent breast reconstruction after mastectomy.⁸ In addition to assessing the benefits of breast reconstruction, it is also essential to collect reliable data on the risks of these procedures. Research that evaluates adverse outcomes assists patients and their surgeons in making informed, appropriate treatment decisions. In today's consumer-oriented health-care marketplace, patients must be thoroughly informed about the types and frequencies of potential complications for any prospective surgical intervention. Failure to obtain such informed consent places providers at considerable medicolegal risk and is

TABLE VII
Logistic Regression of Total Complications

Independent Variable	Odds Ratio (95% confidence interval)	<i>p</i>
Free TRAM flap*	1.50 (0.71 to 3.16)	0.289
Pedicle TRAM flap*	0.90 (0.48 to 1.69)	0.743
Immediate reconstruction	2.16 (1.19 to 3.92)	0.011
Body mass index	1.08 (1.02 to 1.14)	0.005
Age	1.00 (0.97 to 1.03)	0.750
Preoperative radiation	1.66 (0.83 to 3.29)	0.149
Postoperative radiation	2.00 (0.75 to 5.36)	0.167
Chemotherapy	1.26 (0.67 to 2.40)	0.474
Current smoker	0.80 (0.33 to 1.94)	0.620

* The expander/implant group is the reference group.

TABLE VIII
Incidence of Major Complications for Expander/Implant and TRAM Flap Procedures

Timing of Complication	Implants		TRAM Flaps		Combined		<i>p</i>
	No.	%	No.	%	No.	%	
Immediate	30 of 65	46	52 of 145†	36	82 of 210	39	0.158
Delayed	3 of 14	21	18 of 102	18	21 of 116	18	0.730
<i>p</i> *	0.089		0.002		<0.001		

* Values are from chi-square tests.

† Includes one patient who received a free TRAM flap on one side and a pedicle TRAM flap on the other.

widely viewed as ethically unacceptable. Perhaps more importantly, complication data also provide surgeons and health-care organizations with vital feedback to support and guide quality-improvement efforts. Since the work of Ernest Codman in the early twentieth century, complication tracking has served an invaluable role in determining “what works” among medical interventions.⁹ A considerable number of previous investigators have reported complication rates for breast reconstruction procedures.^{10–13} The study presented here addresses several limitations in this existing literature. Although previous reports assessed patients from single surgeons or centers, the Michigan Breast Reconstruction Outcome Study project evaluated women from 23 surgeons and 12 institutions. This design allowed Study investigators to study breast reconstruction outcomes across a variety of practice styles and settings, thereby focusing on procedure choice (rather than surgeon or center) as the primary independent variable affecting outcomes. The use of a multicenter design widens the generalizability of the study results. Unlike most previous studies, the Study project was prospective in design, facilitating systematic data collection and patient follow-up. Preoperative evaluations were conducted to establish baseline scores for the various outcome parameters. After reconstruction, patients were surveyed at fixed intervals, thereby minimizing recall bias and allowing investigators to consistently track changes in outcomes over time. Finally, this study improves on previous reports through its use of

regression analyses to control for potential confounding from a variety of additional independent variables (patient age, body mass index, radiation history, and others) that might impact complication rates.

Although previous reports have noted that complications are not unusual in breast reconstruction,^{10–13} the complication rates observed in the study presented here were strikingly high. For the three types of procedures, immediate reconstructions had total complication rates that ranged from 49 percent to 60 percent, compared with 31 percent to 37 percent for delayed reconstruction procedures. The rates for major complications ranged from 31 percent to 46 percent for immediate procedures and from 16 percent to 21 percent for delayed procedures. The high rates in our study can be attributed to several factors. The inclusion criteria for complications were deliberately broad in an effort to realistically assess the risks associated with reconstruction. For example, we counted a patient as having a postoperative wound infection if she was administered nonperioperative antibiotic treatment (oral or intravenous) for her wounds or if she required incision and drainage of a wound abscess. Also, if a TRAM flap patient underwent abdominal wall reoperation for fascial “laxity,” the complication was labeled a “hernia” in our analysis, because patients and plastic surgeons often do not differentiate between abdominal “laxity” and “hernia.” Likewise, criteria for classification of a complication as major were also deliberately inclusive, encompass-

TABLE IX
Incidence of Major Complications for Pedicle and Free TRAM Flap Procedures

Timing of Complication	Pedicle TRAM Flaps		Free TRAM Flaps		Combined		<i>p</i> *
	No.	%	No.	%	No.	%	
Immediate	30 of 96	31	22 of 48	46	52 of 144	36	0.086
Delayed	15 of 83	18	3 of 19	16	18 of 102	18	0.814
<i>p</i> *	0.043		0.022		0.002		

* Values are from chi-square tests.

TABLE X
Logistic Regression of Major Complications

Independent Variable	Odds Ratio	
	(95% confidence interval)	<i>p</i>
Free TRAM flap*	1.02 (0.47 to 2.23)	0.956
Pedicle TRAM flap*	0.57 (0.29 to 1.11)	0.099
Immediate reconstruction	2.71 (1.35 to 5.44)	0.005
Body mass index	1.12 (1.05 to 1.19)	<0.001
Age	1.00 (0.96 to 1.03)	0.826
Preoperative radiation	1.22 (0.57 to 2.61)	0.606
Postoperative radiation	1.84 (0.69 to 4.96)	0.226
Chemotherapy	1.41 (0.73 to 2.75)	0.310
Current smoker	1.29 (0.51 to 3.27)	0.590

* The expander/implant group is the reference group.

ing any adverse postoperative event that required reoperation, intravenous antibiotic treatment, and/or rehospitalization (because of the relative high cost of these interventions). In addition, unlike most previous reports on breast reconstruction complications, the Outcome Study design used multiple mechanisms to track adverse events, including office-chart and hospital-record reviews and periodic patient surveys, extending to 2 years after surgery. Although this length of follow-up could miss complications that occurred beyond 2 years (not unusual, particularly for implant procedures), extending the follow-up period past the immediate postoperative period likely increased the total number of complications detected.

With regard to the analyses, one of the independent variables that we predicted would have a significant effect on complication rates was the patient's smoking history. Smoking has long been a relative contraindication to many reconstructive procedures. The basic science literature has described the harmful effects of smoking on surgical wounds and flap survival.^{14,15} Many clinical researchers have echoed this sentiment. Higher flap-loss rates, skin slough, and wound-healing complications have been reported in smokers.^{13,16,17} Therefore, it was somewhat surprising that smoking was not found to have a significant effect on complication rates in our population. The significance of our findings is unclear. Although the self-reported assessment of smoking status may be flawed, we have no reason to believe that patients would not be truthful in relating their smoking histories. However, we did not objectively test the patients for nicotine through urine samples. The difference in our findings from other reports on smoking in reconstructive patients may also be explained by previous

studies' lack of controlling for other variables, such as body mass index. Clearly, this issue needs further exploration.

Several researchers have assessed the effect of body mass index on complication rates and have found a positive correlation.^{18,19} For example, the study by Chang et al. of free TRAM flaps in obese patients demonstrated a significant effect of obesity on complication rates, with an odds ratio of 2.75.¹⁸ Our analysis was designed differently in that body mass index was maintained as a continuous variable and examined in three different types of procedures. Despite this difference, our data are supportive of the results by Chang et al. In our study, increasing body mass index was found to be associated with increasing odds of a complication, with an odds ratio of 1.08 for total complications and 1.12 for major complications. This supports a clinically significant association between obesity and the risk of surgical complications.

Based on anecdotal experience, we had expected to find significant effects on complication rates by factors such as patient age, radiotherapy before and after surgery, and chemotherapy. However, evaluation of these independent variables did not show significant effects on the complication rates for the three procedures. Previous research assessing the impact of these factors on breast reconstruction complications is limited. Schuster and coworkers found a 56 percent complication rate in both autogenous and implant reconstructions for patients who received radiotherapy. However, procedure timing was not included as an independent variable in their analysis, nor was there a comparison group of nonradiated patients.²⁰ The Chang et al. study of free TRAM flaps found no significant effect on complication rates by either chemotherapy or radiotherapy.¹⁸ Although common sense requires caution when placing implants in an irradiated surgical site, we did not find a statistically significant higher rate of complications in radiated patients who underwent implant reconstructions. However, we did find a trend for higher complications with both chemotherapy and radiotherapy in TRAM flap and implant reconstructions, respectively. Our limited sample size may contribute to the lack of a statistically significant effect for these two variables on complication rates. Clearly, additional out-

comes research is needed to assess the impact of these clinical factors on the risks of breast reconstruction.

The surgical community's opinion of immediate breast reconstruction has evolved over time. Initially, delayed procedures were favored, allowing women time to psychologically adjust to the mastectomy and, therefore, have a greater appreciation for reconstruction. More recently, patient and surgeon preferences have changed, with immediate reconstructions becoming more popular. However, this evolution of surgical practice has been deficient in research evaluating the effects of procedure timing on patient outcomes. Our analysis suggests that procedure timing has a dramatic influence on complication rates. In TRAM flap reconstructions, immediate procedures were associated with significantly higher complication rates, compared with delayed procedures. Implant patients also had higher complication rates in the immediate relative to the delayed setting, although this difference was not statistically significant—most likely because of the small sample size.

The higher complication rates observed for immediate reconstruction may be attributed to the combination of mastectomy and reconstruction procedures. Reported mastectomy complication rates vary, ranging from 17 percent to 48 percent, with infection rates of 5 percent to 14 percent.²¹⁻²³ Combining these complication rates for mastectomy with this study's complication rates for delayed reconstruction produces a combined complication rate equal to or greater than the complication rates of immediate reconstruction. Therefore, the risk of a combined mastectomy–reconstruction procedure is probably lower than the cumulative complication rate for separate mastectomies and delayed reconstructions. Thus the current study's finding should not be viewed as a basis for advocating delayed over immediate reconstruction. Rather, these results should be used to realistically inform patients, providers, and payers about the risks of reconstructive procedures.

This report has several limitations. As with all cohort designs in clinical studies, the effects observed might be attributable to unknown confounding variables not considered in the study. For example, because procedure types were not uniformly distributed across the par-

ticipating surgeons or centers, it is conceivable that the differences in complication rates noted for procedure types could be explained by individual practice variations among providers. When we explored the complication-rate differences at the site level, using an analytic model that allowed each site to have its own random level of complication, we did not find within-site correlation after adjusting for procedure timing, type, and other variables. The final model reported in this article therefore does not include site as a random effect. Although use of a randomized, controlled design would have reduced the potential impact of these confounders on our analysis, randomizing women across reconstructive procedures is neither practical nor ethical.

This study is also limited by its sources of data. With patient surveys, we relied on respondents to provide accurate information about demographics, personal habits (such as smoking history), and other variables. Although some of this information could be verified through other sources (hospital databases, for example), the reliability of many survey responses could not be corroborated. Likewise, our complication data were only as reliable as their sources (namely, hospital charts, office records, and patient reports). If not detected through one of these mechanisms, complications could have gone unreported. Therefore, the possibility exists that the complications described in this article may be underreported.

CONCLUSIONS

In the Michigan Breast Reconstruction Outcome Study patient population, the most significant factors associated with higher complication rates were timing of reconstruction and body mass index. Both immediate reconstruction and obesity were associated with higher total and major complication rates. No significant differences in complication rates at 2 years' follow-up were noted between implant and autogenous tissue reconstructions or between pedicle and free TRAM flap procedures. Patient age, chemotherapy, and radiotherapy did not seem to have significant effects on complication rates. This report is intended to assist patients and providers in making informed choices for reconstruction after mastectomy.

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