

Early Postoperative Complications From National Surgical Quality Improvement Program

A Closer Examination of Timing and Technique of Breast Reconstruction

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Background: Despite the recent surge in rates of immediate breast reconstruction, there is a paucity of large multicenter studies to compare differences in morbidity after immediate versus delayed breast reconstruction. This study used the National Surgical Quality Improvement Program (NSQIP) to study the association between timing of breast reconstruction and complication rates, stratified by reconstructive modality.

Study Design: The NSQIP database was used to identify breast reconstructions from 2005 to 2012. Rates of major complications were compared by timing within each reconstructive modality (implant vs autologous). Cohort differences in baseline characteristics and variables associated with increased complication rates were identified in bivariate analyses. A multivariable model was created to compare the association between the timing of reconstruction and major complications.

Results: Of 24,506 postmastectomy reconstructions, 85.8% were immediate, 14.2% were delayed, 84% were implant, and 16% were autologous reconstructions. Overall, 10.0% of patients suffered a major complication. After stratification, only implant reconstructions showed a statistically higher complication rate with immediate (8.8%) reconstruction compared with delayed (5.3%) (odds ratio, 1.7, $P < 0.01$). There was no significant difference in complication rates between autologous immediate (18.4%) or delayed (19.0%) reconstructions. After controlling for baseline cohort differences and other risk factors, immediate reconstruction remained as an independent significant predictor of major complications in implant reconstructions (odds ratio, 1.8, $P < 0.01$).

Conclusions: Immediate rather than delayed breast reconstruction is associated with a significantly higher rate of major complications in implant reconstruction but not in autologous reconstruction. It is important to include these findings in the routine preoperative surgeon-patient discussion of reconstructive options.

Key Words: immediate breast reconstruction, delayed breast reconstruction, implant breast reconstruction, autologous breast reconstruction, timing of reconstruction, NSQIP

(*Ann Plast Surg* 2021;86: S159–S164)

There has been a gradual rise in the utilization of both immediate and delayed breast reconstruction in the United States.^{1–3} Although delayed breast reconstruction had been historically more common than immediate breast reconstruction, in the past 2 decades there has been a dramatic increase in the rate of immediate breast reconstruction, population-based rates have nearly doubling in both the United States and Canada (12% in 1998 to 22% in 2008 in the United States; 8% in 1995 to 16% in 2012 in Canada).^{4–10}

The purported advantages of immediate breast reconstruction at the same time as mastectomy include enhanced psychosocial benefits,^{11–14} patient satisfaction,^{11,12,15} and superior cosmesis of the reconstructed breast owing to preservation of breast skin pliability and anatomic landmarks.⁵ Immediate breast reconstruction has been shown to be oncologically safe,^{15,16} and does not negatively impact delivery of adjuvant radiotherapy,^{17–19} nor result in a clinically significant delay in the initiation of chemotherapy for patients with in situ disease or early stage breast cancer.^{20–24} In patients with locally advanced breast cancer, where timely and effective delivery of adjuvant therapy is critical to oncologic outcomes, most oncologists and surgeons advocate for delayed breast reconstruction.²⁵ Delayed breast reconstruction allows patients to focus on their oncologic treatment, provides reassurance about cancer eradication with definitive pathology, and permits increased time to consider reconstructive options.⁵

Despite the increase in immediate breast reconstruction rate, only a handful of studies have directly compared complication rates between immediate versus delayed breast reconstruction. These studies have been limited to retrospective analyses with small sample sizes and have generated mixed findings.^{11,14,26–34} Likely, the most rigorously study that compared between immediate and delayed breast reconstruction was the Mastectomy Reconstruction Outcomes Consortium (MROC) study that used a prospective cohort design to evaluate patients across 11 hospitals in the United States and Canada. The authors found immediate breast reconstruction to have significantly higher failure rates (6% vs 1.3%) compared with delayed breast reconstruction at 2-year follow-up.³⁵

The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) is the most current and comprehensive database of surgical outcomes. The NSQIP systematically and prospectively collects patient demographics, comorbidities, and 30-day postoperative outcomes both in and out of hospital in samplings of patients from hundreds of participating hospitals.³⁶ Previous authors have used NSQIP to compare outcomes after tissue expander reconstruction,³⁷ direct-to-implant reconstruction,³⁸ autologous reconstruction,³⁹ immediate breast reconstruction,^{40–43} delayed breast reconstruction,⁴⁴ and risk factors

Received June 9, 2020, and accepted for publication, after revision September 13, 2020.

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Meeting Presentation: This research has been previously presented at the Canadian Society of Plastic Surgeons meeting on June 5, 2015, in Victoria, British Columbia, Canada.

Financial Disclosures: T.Z. is the inaugural chair holder of the Belinda Stronach Chair in Breast Cancer Reconstructive Surgery at the University Health Network. In addition, she is a Canadian Institutes of Health Research (CIHR) New Investigator Salary Support Award recipient and holder of a Canadian Institute of Health Research (CIHR) Foundation Scheme Program Grant Award. She also receives research project grant funds from the Canadian Breast Cancer Foundation (CBCF)/Canadian Cancer Society (CCS). S.O.P.H. is the Wharton Chair in Reconstructive Plastic Surgery chair holder at the University Health Network.

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ISSN: 0148-7043/21/8602–S159

DOI: 10.1097/SAP.0000000000002590

associated with increased complications in breast reconstruction.^{45,46} The NSQIP database has yet to be used to directly compare complications in breast reconstruction with respect to the timing of reconstruction. Although it is important to equip patients with the knowledge that immediate breast reconstruction may be associated with higher failure rate than delayed breast reconstruction in the long-run, patients also frequently wish to understand the possible rates of short-term complications in the immediate postoperative period.³⁵ The aim of the current study, therefore, is to use the NSQIP database to compare the rates of major complications associated with immediate versus delayed breast reconstruction, for implant and autologous reconstructions separately during the first 30 days after surgery.

METHODS

We used the NSQIP database to identify all cases of female post-mastectomy breast reconstructions from 2005 to 2012 using the 2010 Current Procedural Terminology codes. Implant-based reconstructions were identified by codes for immediate (19340) or delayed (19342) breast prosthesis insertion, immediate or delayed tissue expander insertion (19357), and implantation of biologic implant (eg, acellular dermal matrix, 15777). Autologous reconstructions were identified by codes for breast reconstruction with latissimus dorsi flap without prosthetic implant (19361), transverse rectus abdominis myocutaneous flap (19367, 19368, and 19369), or free flap (19364). International Classification of Diseases diagnostic codes were used to identify and categorize patients with active (174.0–9) or prior history of (V10.3) breast cancer, ductal carcinoma in situ (233), benign breast disease (610.0–9), prophylactic mastectomy (V50.41), genetic susceptibility to malignant breast cancer (V84.01), and encounters of postmastectomy breast reconstruction (V51.0). We excluded atypical reconstructive cases that included a Body Mass Index (BMI) less than 18 ($n = 275$) or greater than 45 ($n = 346$), hospital stays greater than 30 days ($n = 29$), preoperative ventilator dependence ($n = 2$), metastatic disease ($n = 205$), high-risk concurrent surgeries ($n = 1,737$), and emergency surgeries ($n = 69$). The database was accessed on February 24, 2015.

Variables and Outcomes

Of the variables collected in the NSQIP database, the following patient characteristics were selected as independent variables: age, BMI, race, American Society of Anesthesiologist (ASA) score, diabetes, hypertension, smoking, chemotherapy in 30 days before surgery, operating year, admission status, length of hospital stay, timing of reconstruction, and modality of reconstruction. Outcomes of interest were minor and major complications. Minor complications included superficial surgical site infection and wound dehiscence. Major complications included unplanned return to the operating room, deep incision surgical site infection, organ space infection, failure of prosthesis, graft, or flap, bleeding disorder, sepsis, deep vein thrombosis or thrombophlebitis, urinary tract infection, pulmonary embolism, pneumonia, unplanned intubation, peripheral nerve injury, myocardial infarction, stroke or cerebrovascular accident, acute renal failure, cardiac arrest, and coma longer than 24 hours.

Statistical Analysis

Descriptive statistics of all demographic, clinical, and surgical variables were obtained by calculating the mean, standard deviation (SD), and range of continuous variables and frequency of categorical variables. Complications were categorized as minor or major. The association between complication type and timing of reconstruction was analyzed for implant and autologous breast reconstruction separately, using Pearson χ^2 test. Bivariate analysis was performed to examine the association between patient characteristics and each of timing of implant reconstruction and major complications using Pearson χ^2 test for categorical and Wilcoxon rank-sum test for continuous variables.

The association between timing of breast reconstruction and major complication for each type of breast reconstruction was tested using multivariable logistic regression models after controlling for variables that showed significant association with major complications and/or with timing of breast reconstruction. All tests were 2-tailed, and P values of less than 0.05 were deemed significant. All data were analyzed using R 3.2.0.

TABLE 1. Demographic, Clinical, and Surgical Characteristics

Characteristics	Mean	All Cases (n = 24,506)	
		SD	Range
Demographics			
Age	51.5	10.4	18–90
BMI	27.0	5.5	18–45
Total length of hospital stay, d	2.0	1.7	0–29
		n	%
Clinical Characteristics			
Reason for mastectomy			
Cancer		21,289	86.9
Prophylactic		3217	13.1
Diabetes			
Yes		1168	4.8
No		23,338	95.2
Hypertension			
Yes		5944	24.3
No		18,562	75.7
Smoking			
Yes		3091	12.6
No		21,415	87.4
Chemotherapy in last 30 d*			
Yes		924	3.8
No		16,577	67.6
Null		7005	28.6
ASA class			
I and II		19,576	79.9
III and IV		4906	20.0
Unknown		24	0.1
Surgical characteristics			
Timing of reconstruction			
Immediate		21,019	85.8
Delayed		3487	14.2
Reconstructive modality			
Implant		20,595	84.0
Autologous		3911	16.0
Operating year			
2005		276	1.1
2006		961	3.9
2007		1973	8.1
2008		2677	10.9
2009		3512	14.3
2010		3942	16.1
2011		4801	19.6
2012		6364	26.0

* Data regarding chemotherapy and radiation therapy in the designated preoperative period was not available in 7005 (28.5%) and 7024 (28.6%) of cases, respectively.

RESULTS

Study Cohort Characteristics

There were 24,506 cases of female breast reconstruction during the study period (2005–2012). Patient demographic, clinical, and surgical characteristics are summarized in Table 1. Overall, 85.8% of breast reconstructions were immediate, and 14.2% were delayed breast reconstructions. The majority of reconstructions were implant (84.0%) rather than autologous (16.0%) based. Seventy-nine percent of breast reconstruction patients were white. The average breast reconstruction patient age was 51.5 years, and the average BMI was 27.0. Most patients underwent breast reconstruction after therapeutic mastectomy (86.9%) rather than prophylactic mastectomy (13.1%). The mean length of postoperative hospital stay was 2 days. The rate of breast reconstructions after mastectomy increased with each study year, from only 1.1% in 2005 to 26.0% in 2016.

Outcomes

There were 629 cases (2.6%) with minor complications and 2442 cases (10.0%) with major postoperative complications in the first 30 days after breast reconstruction (Table 2). The association between the timing of reconstruction and the incidence of postoperative complications was analyzed. Overall, immediate breast reconstruction was associated with higher odds of major complications than delayed breast reconstruction (odds ratio [OR], 1.19, $P < 0.01$). When stratified by reconstructive modality, there was a significantly higher rate of major complications after immediate (8.8%) compared with delayed (5.3%) reconstruction (OR, 1.72; $P < 0.01$) in the implant reconstruction group, but not in the autologous group (immediate, 18.4%; delayed, 19.0%, $P = 0.76$; Table 3). There was no difference in the incidence of minor complications between immediate or delayed breast reconstructions overall or after stratification by reconstructive modality (Table 3).

The implant reconstruction cohort was further analyzed. Patients who underwent immediate versus delayed implant breast reconstruction were different across a multitude of variables. In particular, 92.1% of

TABLE 2. Complications in Initial 30 Postoperative Days

Complications	n	%
Minor complications*	629	2.6
Superficial surgical site infection	476	1.9
Wound dehiscence	165	0.7
Major complications†	2442	10.0
Surgical		
Return to OR	1174	4.8
Deep incisional surgical site infection	263	1.1
Graft/ prosthesis/flap failure	237	1.0
Organ space surgical site infection	173	0.7
Medical		
Bleeding disorder	392	1.6
Number of Sepsis	111	0.5
Number of Septic Shock	13	0.1
Deep venous thrombosis /Thrombophlebitis	73	0.3
Urinary tract infection	73	0.3
Pulmonary Embolism	55	0.2
Other	66	0.3

*† Breast reconstruction cases with reported minor and major complications as percentage of total reconstructive cases. A given breast reconstruction case may have involved more than one occurrence (eg., multiple wound dehiscence) or subtype of complication (eg, return to OR and deep surgical site infection).

TABLE 3. Comparison of Complications in Immediate Versus Delayed Breast Reconstruction After Stratified by Reconstructive Modality (Autologous Versus Implant)

Complication		Timing of Reconstruction				OR	P
		Delayed		Immediate			
		No.	%	No.	%		
Major	All	No	3184	91.3	18,880	89.8	
	(n = 24,506)	Yes	303	8.7	2139	10.2	1.19 <0.01
	Autologous	No	700	81.0	2485	81.6	
	(n = 3,911)	Yes	164	19.0	562	18.4	0.97 0.76
Implant	All	No	2484	94.7	16,395	91.2	
	(n = 20,595)	Yes	139	5.3	1577	8.8	1.72 <0.01
	Autologous	No	820	94.9	2914	95.6	
	(n = 3,911)	Yes	44	5.1	133	4.4	0.85 0.42
Implant	All	No	2574	98.1	17,569	97.8	
	(n = 20,595)	Yes	49	1.9	403	2.2	1.20 0.25
	Autologous	No	3394	97.3	20,483	97.4	
	(n = 24,506)	Yes	93	2.7	536	2.6	0.95 0.73

immediate implant reconstructions were performed after therapeutic (as opposed to prophylactic) mastectomy compared with only 58.4% in the delayed breast reconstruction group ($P < 0.01$). The majority (75.8%) of immediate implant reconstruction patients were admitted to hospital whereas the majority of delayed implant reconstructions (67.9%) were performed as outpatient surgery ($P < 0.01$). There was no difference in proportion of smokers in each cohort. Table 4 demonstrates that on the bivariate analysis, a large number of clinical and surgical variables were significantly associated with major complications in implant based reconstruction including increased age, BMI, presence of diabetes, hypertension, smoking, higher ASA level, therapeutic (as opposed to prophylactic) mastectomy, in addition to immediate timing of reconstruction.

The final multivariable model comparing major complications after immediate versus delayed implant reconstruction is shown in Table 5. After controlling for baseline characteristics that were significantly associated with major complications, the timing of reconstruction remained an independent and significant predictor of major complications after implant breast reconstruction. Patients undergoing immediate reconstruction had almost twice the odds of sustaining a major complication compared with those undergoing delayed reconstruction when implants were used (OR, 1.78, $P < 0.01$). Other variables that also significantly increased the odds of major complications in implant reconstruction included smoking (OR, 1.57, $P < 0.01$), higher ASA class (OR, 1.18, $P < 0.01$), hypertension (OR, 1.17; $P = 0.02$), and higher BMI (OR, 1.04; $P < 0.01$).

DISCUSSION

Using the NSQIP database, we found that when implants were used, immediate breast reconstruction was significantly associated with increased odds of major complications compared with delayed breast reconstruction by nearly 2-fold (OR, 1.72; $P < 0.01$). This association was not found for autologous reconstruction. These findings are vital for inclusion in the preoperative surgeon-patient discussion when comparing the complication profiles between implant and autologous reconstruction, as well as deciding between immediate versus delayed reconstruction. Furthermore, recent population based studies revealed implant based reconstruction as the leading form of breast reconstruction after 2002 and this trend further surged after the re-approval of silicone implants in 2006 by the Food and Drug Administration.^{7,47,48}

TABLE 4. Association of Variables and Major Complications After Implant Breast Reconstruction

Characteristics	Major Complication				P
	No (n = 18,879)		Yes (n = 1,716)		
	No.	%	No.	%	
Clinical					
Reason for Breast Reconstruction					
Cancer	16,533	87.6	1546	90.1	<0.01
Prophylactic	2346	12.4	170	9.9	
Diabetes					
Yes	873	4.6	101	5.9	0.02
No	18,006	95.4	1615	94.1	
Hypertension					
Yes	4380	23.2	520	30.3	<0.01
No	14,499	76.8	1196	69.7	
Smoking					
Yes	2389	12.7	318	18.5	<0.01
No	16,490	87.3	1398	81.5	<0.01
ASA Class					
I & II	15,310	81.1	1283	74.8	<0.01
III & IV	3553	18.8	428	24.9	
Unknown	16	0.1	5	0.3	
Surgical					
Timing					
Delayed	2484	13.2	139	8.1	<0.01
Immediate	16,395	86.8	1577	91.9	
Demographics					
	Mean (SD)	Range	Mean (SD)	Range	P
Age	51.3 (10.6)	18–90	52.3 (10.5)	18–90	<0.01
BMI	26.5 (5.5)	18–45	28.2 (6.1)	18–45	<0.01

Therefore, patients who will undergo immediate implant-based reconstruction now make up the largest proportion of breast reconstruction candidates in North America and should be informed of the findings from this NSQIP study, which have direct implications on their surgical outcomes. On the one hand, although it is important that immediate reconstruction may yield superior postoperative psychosocial benefits as well as aesthetic outcomes compared with delayed,^{11–15} it is equally imperative that patients are counseled of the higher morbidity associated with the immediate timing of reconstruction compared with delayed reconstruction, in the setting of implant reconstruction.

The timing of reconstruction did not exert a significantly different influence in the rate of major complications for autologous reconstruction. The most likely explanation for similar complication rates is that regardless of the timing of autologous reconstruction, the surgeons have to operate on both the mastectomy site and a flap donor site. In both the immediate and delayed settings, the majority of the operation is the same (elevating the flap, inseting, and shaping the flap) for a pedicled reconstruction, and the additional anastomosis of the recipient and donor vessels together for a microsurgical reconstruction. However, since autologous reconstructions involve an additional donor surgical site and increased operative time, they have previously been shown to be an independent risk factor for major complications in breast reconstruction.⁴⁵ This is consistent with our finding that the incidence of major complications with autologous reconstruction (18.4% in immediate and 19.0% in delayed) was much higher than those with implant reconstruction (8.8% in immediate and 5.3% in delayed), regardless of timing of reconstruction.

Several groups have used the NSQIP to determine complications associated with different elements of breast reconstruction.^{36–40,42–45} Fischer et al.⁴⁵ analyzed breast reconstruction cases from 2005–2010 NSQIP databases with outcomes organized into surgical, medical, or wound complications. They identified immediate reconstruction as an independent predictor of major surgical complications and autologous reconstruction as an independent predictor of wound, medical, and major surgical complications. Our study provides an update to this analysis with incorporation of an additional 2 years of data equivalent to 8443 breast reconstructive cases. Furthermore, we specifically compared complications rates separately for immediate and delayed reconstruction, stratified by reconstructive modality. We also examined major and minor complications separately, since most surgical patients may be more tolerant of minor complications and less tolerant of major complications that have serious adverse effects on their health outcomes.

Earlier studies examining the effect of breast reconstruction timing on complication rates have yielded variable results. Sullivan et al.³³ reported a similar modality-specific effect of timing on complications as our study: implant reconstructions had higher rates of complications in immediate (51.7%) than delayed (49.1%, $P = 0.008$) reconstruction, whereas no effect of timing was observed in autologous breast reconstructions (immediate 52.4% vs delayed 36.4%, $P = 0.70$). Alderman et al.²⁶ in their multicenter cohort analysis reported a reverse trend with no significant effect of timing of reconstruction on major complications in implant reconstruction (46% immediate vs 21% delayed, $P = 0.089$), but significantly higher rate of major complications in immediate (36%) compared with delayed (18% delayed breast reconstruction, $P = 0.002$) autologous reconstructions. One key factor that contributes to differences in results of these prior studies is heterogeneity of their selected outcome measures. Whereas Sullivan et al. studied reconstructive-specific complications (eg, seromas, hematomas, capsular contractures, implant malposition and deflation, etc.); Alderman

TABLE 5. Multivariable Regression Model for Comparison of Major Complications After Immediate Versus Delayed Implant Reconstructions

Variable	OR	95% CI	P
Timing			
Delayed			
Immediate	1.78	1.48–2.16	<0.01
Reason for Breast Reconstruction			
Prophylactic			
Cancer	1.03	0.89–1.23	0.73
ASA			
I & II			
III & IV	1.18	1.04–1.33	<0.01
Hypertension			
No			
Yes	1.17	1.03–1.32	0.02
Diabetes			
No			
Yes	0.90	0.71–1.12	0.35
Smoker			
No			
Yes	1.57	1.38–1.79	<0.01
Age	1.00	1.00–1.01	0.10
BMI	1.04	1.04–1.05	<0.01

95% CI, 95% confidence interval.

et al. used broader variables that reflect major surgical and medical postoperative complications (eg., re-operation, re-hospitalization, and IV antibiotics). The most recent and rigorous study that compared between immediate and delayed breast reconstruction was the MROC study, which found immediate breast reconstruction to yield significantly higher failure rates (6% vs 1.3%) compared with delayed breast reconstruction at 20-year follow-up.³⁵ An important difference that distinguishes our current study is the inclusion of more contemporary reconstruction data (2005–2012) from 371 hospitals in the United States and Canada compared with the Alderman and Sullivan studies. Furthermore, our short-term complication comparison between immediate and delayed breast reconstruction stratified by the method of reconstruction supports similar findings on the long-term complications generated by the MROC study.³⁵

Strengths

The large cohort of patients from a multitude of institutions in the NSQIP captures differences that may otherwise be undetected and transcends confounders such as surgeon and institutional practices to yield results with high generalizability. Additionally, relatively early follow-up protocol minimizes recall bias and systematic collection by trained researchers aims to eliminate any observer bias. No previous study has *a priori* intended to examine the relationship between immediate and delayed breast reconstruction, separately for implant and autologous reconstructions. The 2 reconstructive modalities vary in the incidence, timing, and type of postoperative complications²⁶ as well as patient selection, therefore by stratifying the modality type for each timing of reconstruction before analysis, we were able to demonstrate differential effect of timing based on reconstructive modality, even after controlling for the potential confounders in our final multivariable model.

Limitations

There are several limitations to this study inherent in the NSQIP database and study period selected being already a number of years old. The NSQIP database has been developed to capture general medical and surgical postoperative complications, and does not capture reconstruction-specific complications. Other studies of immediate versus delayed breast reconstruction report significantly higher rates of complications after breast reconstruction ranging from 32% to 52%,^{26,33} which is significantly higher than complication rates from the NSQIP database. Additionally, the 30-day postoperative follow-up period in the NSQIP does not capture the longer-term complications that may cause patient-distress such as implant malposition, capsular contracture, fat necrosis and donor site contour deformity that require secondary operation. Therefore, NSQIP underreports reconstructive-specific and long-term complications. Lastly, the NSQIP database does not collect information regarding psychosocial well-being, patient satisfaction, and esthetics, which are outcomes of particular interest to plastic surgeons and patients and may constitute the primary motivating factors for immediate breast reconstruction. Despite rigorous data collection protocols in the NSQIP, there was a lack of sufficient data on preoperative chemotherapy or radiation therapy in patients undergoing breast reconstruction, with nearly 30% missing data. As a result, preoperative radiation and chemotherapy could not be included nor controlled for in our multivariable model. Preoperative chemotherapy and radiation therapy are associated with increased risk of postoperative complications.⁴³

CONCLUSION

Timing and modality of reconstruction constitute the main decision nodes in breast reconstruction planning. There have been tremendous changes in the breast reconstruction frontier in recent years, with immediate implant-based reconstruction becoming the leading reconstructive method.³ Although complication is an important outcome to measure

in breast reconstruction, there are other valuable patient-reported outcomes to consider such as the quality of life, patient satisfaction, and esthetic outcomes. In this study, we have shown that the odds of sustaining major short-term complications were significantly greater when performed immediately rather than in a delayed fashion in implant-reconstruction, while this association was not found for autologous reconstruction. These NSQIP study findings are consistent with findings on the long-term complications generated by the MROC study which found that at 2 years after surgery, immediate breast reconstruction is also significantly associated with higher rates of reconstructive failure compared with delayed reconstruction.³⁵ It is imperative that these findings are included in the routine preoperative surgeon-patient discussion of reconstructive options.

ACKNOWLEDGMENT

The authors would like to thank our biostatisticians, Shaghayegh Bagher, MSc and Xi Liu, BSc, MSc, PhD, for their contributions in data collection and analysis overview.

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