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ORIGINAL ARTICLE – BREAST ONCOLOGY

A Comparison of Surgical Complications Between Immediate Breast Reconstruction and Mastectomy: The Impact on Delivery of Chemotherapy—An Analysis of 391 Procedures

Toni Zhong, MD[1], Stefan O. P. Hofer, MD[1], David R. McCready, MD[2], Lindsay M. Jacks, MD[3], Francis E. Cook, MD[4], and Nancy Baxter, MD[5,6]

[1]Division of Plastic and Reconstructive Surgery, Department of Surgery, University Health Network, University of Toronto, Toronto, ON, Canada; [2]Department of Surgical Oncology, Department of Surgery, University Health Network, University of Toronto, Toronto, ON, Canada; [3]Department of Epidemiology and Biostatistics, University Health Network, University of Toronto, Toronto, ON, Canada; [4]Department of Epidemiology, Harvard School of Public Health, Boston, MA; [5]Departments of Surgery and Health Policy, Management, and Evaluation, University of Toronto, Toronto, ON, Canada; [6]Keenan Research Centre, Li Ka Shing Knowledge Institute, St Michael's Hospital, Toronto, ON, Canada

ABSTRACT

Purpose. To compare the postoperative complications after immediate breast reconstruction (IBR) versus mastectomy alone and to examine the impact on the delivery of chemotherapy.

Methods. In this prospective series, there were 391 consecutive women who underwent mastectomy (243 mastectomy alone and 148 mastectomy and IBR). The outcome measures were complications (within 3 months after surgery) and time to adjuvant chemotherapy.

Results. Compared to the IBR group, patients in the mastectomy alone group were significantly older ($P < 0.0001$), smokers ($P = 0.007$) and less likely to have had previous radiation or lumpectomy ($P < 0.0001$). Overall, the complication rate was significantly greater in the IBR group than mastectomy alone (27.0% vs. 15.6%, $P = 0.009$). Univariate analyses revealed that mastectomy with IBR [odds ratio (OR) = 2, 95% confidence interval (CI) 1.21–2.30]; bilateral procedure (OR = 1.84, 95% CI 1.07–3.16); previous radiotherapy (OR = 2.4, 95% CI 1.29–4.47); and previous lumpectomy (OR = 1.84, 95% CI 1.11–3.03) were significant predictors of increased complications. With multivariable analysis, none of these variables were significantly associated with increased complications. 106 patients received adjuvant chemotherapy; median time from mastectomy to chemotherapy was 6.8 (0.71–15) weeks in the mastectomy alone group ($n = 96$) compared to 8.5 (6.3–11) weeks in the IBR group ($n = 10$) ($P = 0.01$).

Conclusions. Although the incidence of overall and major postoperative complications was higher after IBR than mastectomy alone, there were no significant relationships in the multivariable analysis. IBR was associated with a modest increase in time to chemotherapy that was statistically but not clinically significant.

The goal of postmastectomy breast reconstruction is to restore a breast mound and to maintain health related quality of life in breast cancer survivors without affecting the prognosis or detection of cancer recurrence.[1–4] A variety of immediate breast reconstructive techniques coupled with skin-sparing mastectomies have resulted in superior aesthetic outcomes with minimal disruption to the patient's lifestyle.[5] Immediate breast reconstruction (IBR) is available to women diagnosed with early-stage breast cancer, and one that should be considered when contemplating breast conservation therapy versus mastectomy.[6–10] Just as the role of IBR is expanding, adjuvant chemotherapy is also being used increasingly in women with early stage breast cancer.[11] Adjuvant chemotherapy in appropriately selected breast cancer patients, delivered in a timely fashion after mastectomy, can provide benefits in decreasing recurrence and improving survival.[12]

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T. Zhong, MD
e-mail: Toni.zhong@uhn.on.ca

Despite the advantages of IBR, less than 20% of women in the United States received breast reconstruction at the same time as mastectomy.[13] One barrier to IBR is the concern that postoperative complications after reconstruction may lead to a delay in the initiation of chemotherapy or even result in its omission.[14] To date, the studies that have examined IBR and the impact on initiation of chemotherapy have yielded conflicting results. Allweis et al. compared women who underwent IBR to those who underwent mastectomy alone and found that time to chemotherapy was longer in the group receiving no reconstruction (53 vs. 41 days).[15] Mortenson et al. studied 128 women who were treated with a mastectomy with or without IBR, and found that although there was a higher incidence of wound complications in the IBR group (22.3% vs. 8.3%), there was no delay in the initiation of postoperative chemotherapy.[16] In a study from eight National Comprehensive Cancer Network institutions, IBR was associated with a statistically significant delay in the initiation of chemotherapy. Although the authors concluded that the modest delay was unlikely to have any clinical significance, this study raises an important question of whether delay in adjuvant chemotherapy initiation is associated with higher postoperative complication rates with IBR compared to mastectomy alone.[17]

The purpose of this study was to compare the postoperative complications in patients after IBR versus mastectomy alone, and to examine the impact of the two types of surgeries on the delivery of chemotherapy.

METHODS

Patients

After receiving approval from the institutional ethics review board, a consecutive series (May 1, 2007 through June 31, 2010) of women undergoing mastectomy at the University Health Network, Toronto, Canada were identified by means of a prospectively maintained institutional breast database. Demographic, cancer related treatment, and surgical data were obtained from this database. Demographic data included age at diagnosis, date of surgery, tobacco use, body mass index (BMI), and comorbidities. Oncologic data included breast cancer status (prophylactic or benign breast disease, in situ disease, invasive carcinoma, or other), previous radiation and chemotherapy status, and active hormonal treatment. Surgical data included date of surgical intervention, type of surgery (mastectomy alone or IBR), sentinel lymph node biopsy (SLNB), axillary lymph node dissection (ALND) (sentinel vs. complete dissection), laterality, and type of reconstructive procedures (implant based vs. autologous tissue vs. mixed). Patients were excluded if they had neoadjuvant chemotherapy as preoperative chemotherapy can adversely affect wound healing.

Surgery

Our selection criteria for timing and method of IBR are consistent with previously published guidelines.[9,18,19] In brief, IBR was usually offered to women with a strong family history or gene positivity for breast cancer, in-situ breast cancer, or clinical stage I or IIa breast cancer when postmastectomy radiotherapy is not likely to be required postoperatively. The selection of the technique of IBR was based on location and type of cancer and extent of resection, patient's medical and surgical risk factors, need for adjuvant radiotherapy, availability of local and distant donor tissue, desired size and shape of the reconstructed breast, and most importantly, patient preference. In general, autologous tissue reconstruction was offered to women who had undergone prior breast irradiation, available donor tissues, previous lumpectomy scars, nonpliable chest wall soft tissues, and those who requested this type of surgery. Breast surgery was performed by five surgical oncologists, and IBR was performed by two plastic surgeons (T.Z., S.H.). All patients routinely received standard prophylactic intravenous antibiotics before skin incision, typically 1 g of cefazolin or 600 mg of clindamycin if allergic to penicillin.

Outcome Measures

The primary outcome was any postoperative complication (minor or major) within 3 months. A postoperative complication was defined as an adverse event which occurred as a direct consequence of surgery and required additional treatment beyond that normally associated with the procedure. Major complications were those that required reoperation for any reason, prolonged hospital stay or readmission to hospital or a major medical complication (such as pulmonary embolus). Minor complications included drainage of seroma in the clinic, treatment of cellulitis with oral antibiotics, delayed wound healing which required dressing changes longer than three weeks, minor debridement of mastectomy flap necrosis, or minor medical complications such as exacerbation of asthma or atelectasis. Complication data were abstracted from two sources (the prospective database and the electronic patient record).

In patients with invasive cancer, the secondary outcomes evaluated were time to adjuvant chemotherapy and number of patients found to have delay in starting adjuvant chemotherapy. Time to adjuvant chemotherapy was reported as a continuous variable measured from the last

definitive breast surgery (mastectomy or therapeutic axillary lymph node dissection) to the first dose of adjuvant chemotherapy. A delay in start of chemotherapy was defined as the time greater or equal to 12 weeks after the final definitive breast surgery. This time-frame was selected on the basis of results that found equivalent survival between patients who received chemotherapy at three weeks compared to 12 weeks postoperatively.[20,21] The decision to administer postoperative adjuvant chemotherapy, the specific regimen, and its duration was made by the medical oncologist on the basis of cancer-related factors and patient preference.

Statistical Analysis

Patient and surgical characteristics were summarized and compared between the mastectomy only and mastectomy and IBR groups by Fisher's exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. The incidence of complications (minor, major, overall) within the first 3 months after surgery was compared between surgical intervention groups by Fisher's exact test. Univariate and multivariable logistic regression were used to examine the risk factors associated with complications (minor or major). Factors included in the univariate analyses were age at diagnosis, BMI (grouped as <25, 25–30, >30), previous tobacco use (yes/no), comorbidity (yes/no), breast cancer status (prophylactic or benign breast disease, in situ disease, invasive carcinoma, or other), previous breast irradiation (yes/no), previous lumpectomy (yes/no), SLNB (yes/no), and ALND (yes/no). Those factors found to be significant on univariate analysis ($P < 0.05$), and variables considered a priori to affect complication rates (BMI and previous tobacco use), were included in the multivariable analysis. Because previous lumpectomy and previous breast irradiation were highly correlated, only previous irradiation was included in the regression model. An interaction variable was created to combine the type of surgery with laterality into a single interaction variable "surgery/laterality" to allow the effect of laterality to be different for the mastectomy alone group from mastectomy and IBR group.

For patients with advanced invasive breast cancer who required adjuvant chemotherapy, time to adjuvant chemotherapy was compared between surgical intervention groups by the Wilcoxon rank sum test. The frequency of patients who experienced a delay was compared between surgical intervention groups by Fisher's exact test. A P value of<0.05 was considered statistically significant, and all P values were two-sided. All statistical analyses were performed by SAS software, version 9.2 (SAS Institute, Cary, NC).

RESULTS

There were 391 women who underwent mastectomy from May 1, 2007 through June 31, 2010 and 148 (38%) patients underwent mastectomy and IBR and 243 (62%) underwent mastectomy alone. There were statistically significant differences between the two groups in terms of patient characteristics (Table 1). Compared to patients with IBR, patients having mastectomy alone were older (median age 51 vs. 45 years, $P < 0.0001$), smokers (14% vs. 5%, $P = 0.007$) and more likely to have a unilateral procedure (94% of mastectomy alone procedures, 47% of IBR procedures, ($P < 0.0001$)). Patients having IBR were more likely to have had a previous lumpectomy (58% vs. 28% $P < 0.0001$) and previous radiation to the breast (34% vs. 2%, $P < 0.0001$). There were 47% of IBR patients with a diagnosis of invasive breast cancer and 93% of mastectomy alone patients with invasive breast cancer ($P < 0.0001$). The rates of SLNB and complete ALND were significantly higher in the mastectomy alone (40, 55% respectively) compared to the IBR group (13, 19%) ($P < 0.0001$). In the IBR group, 39% had tissue expander or implants alone, 55% had microsurgical autologous tissue transfer techniques, and 6% had pedicled latissimus dorsi with tissue expander or implant.

Postoperative complications occurred in 78 of 391 patients (19.9%): 13.8% had minor complications only, 8.2% had major complications only, and 8 (2.0%) had both a major and minor complication. In the patients undergoing mastectomy alone, 3.7% had a major complication compared to 15.5% in the IBR group ($P < 0.0001$). The overall incidence of postoperative complications was significantly higher in the IBR compared to mastectomy alone group (27.0% vs. 15.6%, $P = 0.009$). This was primarily due to a higher incidence of major complications in patients undergoing IBR (15.5%) compared to mastectomy alone (3.7%, $P < 0.0001$). In both groups, the most common minor complication was seroma formation that required drainage and the most common major complication was reoperation for any reason; hematoma evacuation was the most common procedure (Table 2). There were three major medical complications in the IBR group; pulmonary embolism ($n = 1$) and Clostridium Difficile colitis ($n = 2$). There were four cases of partial or total flap failure and three cases that necessitated implant or tissue expander removal resulting in a 5% reconstructive failure rate.

Univariate logistic regression was performed to analyze the impact of each factor on the overall rate of postoperative complications (Table 3). Mastectomy with IBR [odds ratio (OR) = 2, 95% confidence interval (CI) 1.21–2.30], bilateral procedure (OR = 1.84, 95% CI 1.07–3.16), previous breast irradiation (OR = 2.4, 95% CI 1.29–4.47) and

TABLE 1 Patient characteristics, overall and by treatment group

Characteristic	Mastectomy alone ($n = 243$)	Mastectomy and IBR ($n = 148$)	P value[a]
Age at diagnosis (year)			<0.0001
Median (range)	51 (31–88)	45 (20–68)	
<60 (%)	169 (70)	136 (92)	
≥60 (%)	74 (30)	12 (8)	
BMI (kg/m^2)			
Median (range)	25.0 (18.9–49.2)	24.9 (15.9–40.0)	0.85
<25 (%)	94 (39)	75 (51)	0.73
25–30 (%)	63 (26)	44 (30)	
>30 (%)	31 (13)	28 (19)	
Unknown (%)	55 (23)	1 (1)	
Tobacco use			0.007
Yes (%)	35 (14)	8 (5)	
No (%)	208 (86)	139 (94)	
Unknown	0	1 (1)	
Comorbidity			0.68
Yes (%)	122 (50)	71 (48)	
No (%)	121 (50)	77 (52)	
Breast cancer status			<0.0001
Prophylactic and benign breast disease (%)	1 (0.4)	39 (26)	
In situ disease (%)	12 (5)	39 (26)	
Invasive (%)	227 (93)	69 (47)	
Other (%)	3 (1)	1 (1)	
Previous radiation to breast (%)	5 (2)	51 (34)	<0.0001
Previous lumpectomy (%)	68 (28)	86 (58)	<0.0001
Active hormone therapy (%)	79 (33)	46 (31)	0.82
Laterality of surgery			<0.0001
Unilateral (%)	229 (94)	69 (47)	
Bilateral (%)	14 (6)	79 (53)	
Axillary lymph node procedure			<0.0001
None (%)	10 (4)	101 (68)	
SLNB only(%)	98 (40)	19 (13)	
ALND (with or without SLNB) (%)	134 (55)	28 (19)	
Unknown (%)	1 (0.4)	0	

[a] Fisher's exact test for categorical variables; Wilcoxon rank sum test for continuous variables; unknowns excluded

TABLE 2 Complications within 3 months by treatment group

Complication	Mastectomy alone	Mastectomy and IBR
Minor		
Total no.	31	23
Seroma (%)	30 (97)	10 (43)
Mastectomy flap necrosis (%)	0	3 (13)
Debridement for any wounds (%)	1 (3)	4 (17)
Donor site complications (%)	0	6 (26)
Major		
Total no.	9	23
Reoperation for any reason (%)	9 (100)	12 (52)
Rehospitalization for any reason (%)	0	1 (4)
Implant or tissue expander removal (%)	0	3 (13)
Flap failure (total or partial) (%)	0	4 (17)
Major medical complications (%)	0	3 (13)

previous lumpectomy (OR = 1.84, 95% CI 1.11–3.03) were statistically significant predictors of increased complications, whereas SLNB was associated with a decreased probability of complications (OR = 0.57, 95% CI 0.33–0.98) (Table 3). In the multivariable model, after adjusting for laterality, BMI, smoking, previous breast irradiation, and sentinel lymph node dissection, IBR was no longer a significant predictor of increased complications (OR = 1.31, 95% CI 0.63–2.76). However, the interaction term that combined the type of surgery with laterality, revealed that bilateral IBR was associated with significantly more complications compared to unilateral mastectomy alone (OR = 2.12, 95% CI 1.06–4.27).

There were 106 patients with invasive breast cancer who received adjuvant chemotherapy; mastectomy alone ($n = 96$, 39.5%), IBR ($n = 10$, 6.8%). The median time from the last definitive breast surgery to start of chemotherapy was 6.8 (0.7–15.0) weeks in the mastectomy alone group compared to 8.5 (6.3–11.0) weeks in the IBR group ($P = 0.01$) (Table 4). In total, two (2.1%) patients in the mastectomy alone group and none in the IBR group had a delay in the start of chemotherapy beyond 12 weeks from time of the mastectomy. One patient chose to delay the start of chemotherapy for personal reasons, and the other patient had a postoperative infected hematoma after her mastectomy that may have delayed her consultation with medical oncology.

DISCUSSION

At our institution, IBR was performed by two plastic surgeons who routinely use all types of reconstructive methods and the final choice of reconstruction is dependent on careful patient-procedure selection. The rate of overall postoperative complications between both groups was significantly different (27.0% for mastectomy with IBR vs. 15.6% for mastectomy alone, $P = 0.009$) and the rates were comparable to those previously reported.[16,22–24] Mortensen et al. reported higher rates of wound complications in the IBR group than mastectomy alone (22.3% vs. 8.3%), as well as the large series of more than 400 patients

TABLE 3 Univariate and multivariable logistic regression analysis for predictors of complications

Variable	Univariate		Multivariable	
	OR	95% CI	OR	95% CI
Type of surgery				
Mastectomy alone	1.00		1.00	
Mastectomy and IBR	2.00	1.21–3.30	1.31	0.63–2.76
Laterality				
Unilateral	1.00		1.00	
Bilateral	1.84	1.07–3.16	1.54	0.78–3.04
Type of surgery/laterality				
Mastectomy alone/unilateral	1.00		1.00	
Mastectomy alone/bilateral	0.40	0.05–3.15	0.47	0.06–3.85
Mastectomy and IBR/unilateral	1.44	0.74–2.82	1.09	0.48–2.43
Mastectomy and IBR/bilateral	2.40	1.33–4.34	2.12	1.06–4.27
Age at diagnosis	0.99	0.97–1.02		
BMI (kg/m^2)				
<25	1.00		1.00	
25–30	0.67	0.36–1.27	0.68	0.36–1.31
>30	1.22	0.61–2.43	1.24	0.61–2.52
Tobacco use				
No	1.00		1.00	
Yes	1.24	0.58–2.65	1.85	0.81–4.22
Comorbidity				
No	1.00			
Yes	0.97	0.59–1.59		
Breast cancer status				
Prophylactic/benign breast disease	1.00			
In situ disease	0.73	0.27–1.98		
Invasive	0.72	0.33–1.55		
Other	1.00	0.09–10.74		
Previous breast irradiation				
No	1.00		1.00	
Yes	2.40	1.29–4.47	1.87	0.91–3.85
Previous lumpectomy				
No	1.00			
Yes	1.84	1.11–3.03		
Sentinel lymph node biopsy				
No	1.00		1.00	
Yes	0.57	0.33–0.98	0.81	0.42–1.55
Axillary lymph node dissection				
No	1.00			
Yes	0.80	0.48–1.33		

OR odds ratio, *IBR* immediate breast reconstruction

by O'Brien et al. (31% after IBR vs. 28% mastectomy alone).[16,22] However, in our multivariable regression analysis, immediate reconstruction was not associated with increased postoperative complications.

In our study, patients in the IBR group were more likely to have one or more major complications compared to patients having mastectomy alone (15.5% vs. 3.7%, $P < 0.0001$) but there was no difference in minor complications between the surgical groups. The most common major complication in the IBR group was hematoma evacuation and anastomotic revision in microsurgical reconstructions. Complete microsurgical flap loss rate was 2.7%, which was comparable to 2% reported by Zweifel-Schlatter et al.[25] Our total implant loss rate was 2.0% which was comparable to the 2.7% premature implant removal rate reported by McCarthy in the first year after surgery, but lower than other smaller series (14–38% implant failure rate), which may be related to our relatively short follow-up period.[26–28]

After controlling for the effect of covariates which may contribute to complications, IBR with mastectomy was not associated with a higher incidence of complications compared to mastectomy alone (OR = 1.31, 95% CI 0.63–2.76). However, the interaction of surgery group with laterality revealed that bilateral IBR procedures had an increased rate of complications compared to unilateral mastectomy alone (OR = 2.12, 95% CI 1.06–4.27). The increased number of operative sites and duration of the surgery associated with bilateral procedures may contribute to the likelihood of complications. In a previous study conducted at our center, longer duration surgeries were associated with early postoperative complications after microsurgical reconstruction for breast cancer.[29] In a retrospective review, Rao et al. also reported a higher incidence of failure rates with bilateral microsurgical breast reconstruction compared to unilateral reconstruction (3.5% vs. 2.1%) and this was attributed to the increased technical challenges associated the use of bilateral lower abdominal tissue for free tissue transfer.[30]

The studies that have examined IBR and its impact on the initiation of chemotherapy have yielded conflicting results. Our series identified a total of 106 patients who received adjuvant chemotherapy, and of these, 96 (39.5%) had mastectomy alone and 10 (6.8%) had IBR. Although the median time to initiation of chemotherapy was found to be significantly longer with IBR (8.5 weeks) compared to mastectomy alone (6.8 weeks) ($P < 0.01$), no patients in the IBR group (range of 6.39 to 11.0 weeks) had a clinical delay in starting adjuvant chemotherapy. This was in agreement with a multicenter National Comprehensive Cancer Network cohort study which showed a statistically significant delay in median time to chemotherapy after IBR (6 weeks) compared to mastectomy alone (5 weeks) in patients under 60 years of age.[17] The median time to chemotherapy was approximately 2 weeks longer in our single Canadian institutional study in both the mastectomy alone (6.8 vs. 5 weeks) and mastectomy with IBR groups (8.5 vs. 6 weeks) than observed in the National Comprehensive Cancer Network multicenter study of Alderman et al.[17] Although guidelines dictating the initiation of chemotherapy were not investigated in this study, it

TABLE 4 Interval of time between last definitive breast surgery and initiation of chemotherapy

Characteristic	Mastectomy alone	Mastectomy and IBR	*P* value[a]
No. of patients	243	148	–
Receiving chemotherapy, *n* (%)	96 (39.5)	10 (6.8)	–
Initiation of chemotherapy, week from surgery, median (range)	6.79 (0.71–15.00)	8.50 (6.29–11.00)	0.01
Delay in initiation of chemotherapy, ≥12 week, *n* (%)	2 (2.1%)	0	1.00

[a] Fisher's exact test for categorical variable; Wilcoxon rank-sum test for continuous variable

appears that there may be institutional and even national differences in how early after ablative surgery chemotherapy is administered. At our institution, the decision to offer a patient IBR is one that is made in consultation with a multidisciplinary team including the plastic surgeon, breast surgeon, and medical and radiation oncologists. This approach is used to ensure that IBR is reserved for appropriately selected patients and to avoid deleterious outcomes such as delay of adjuvant chemotherapy. Most importantly, our conclusion is congruent with that of Alderman and group that a 1 or 2 week delay in the initiation of adjuvant chemotherapy that is otherwise administered within proven time frames is unlikely to impact long-term survival.[17]

Our study investigated the incidence of postoperative morbidity in terms of minor and major complications. This is an important distinction because increased minor complications may be an acceptable risk of IBR, whereas an increased rate of major complications may be unacceptable, particularly if it interferes with the timely delivery of adjuvant chemotherapy. Adding to the strength of our investigation, this study is the first to perform a multivariable regression analysis to investigate the relationship between patient, disease, and surgical factors that may lead to increased risk of complications after mastectomy and IBR. Limitations to this study include its observational nature, so factors that were not investigated may be associated with both treatment choice and postoperative complications. Also, 23% of the mastectomy-only patients had no BMI data, which could affect our assessment of the complication rates for this group, thus lowering the statistical power to assess this variable. In addition, there was a limited number of bilateral mastectomy alone patients ($n = 14$) in this study in the combined "surgery/laterality" analysis in which we attempted to disentangle the effect of laterality from the surgery type. Our secondary analysis of impact of IBR on initiation of chemotherapy needs to be interpreted with caution because there were only 10 patients in this group. The small number of patients in this group reflects our careful selection of patients for IBR who have less advanced breast cancer. It is, however, reassuring is that our results are consistent with a larger multicenter cohort study conducted by Alderman et al. that there was a modest statistically significant delay in initiation of chemotherapy that was still within the proven time frame after IBR compared to mastectomy alone.[17] Last, because our outcomes reflect the experience of a single high-volume breast cancer center with a focus on microsurgical reconstruction, it may not be generalizable to other settings.

In conclusion, the incidence of overall and major postoperative complications was higher after IBR than mastectomy alone; however, there was no statistically significant relationship between IBR and postoperative complications in the multivariable analysis. Bilateral IBR procedures were associated with significantly more complications compared to unilateral mastectomy. IBR was found to be associated with a modest increase in time to chemotherapy initiation that was statistically significant, but there was no incidence of clinically meaningful delay of beyond 12 weeks in the IBR group. On the basis of these findings, patients who wish to have bilateral IBR must be counseled about the higher likelihood of increased postoperative complications than undergoing mastectomy alone, particularly in those with invasive breast cancer who are anticipated to require adjuvant chemotherapy.

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