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ORIGINAL ARTICLE – BREAST ONCOLOGY

Long-Term Patient-Reported Satisfaction after Contralateral Prophylactic Mastectomy and Implant Reconstruction

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ABSTRACT

Purpose. To determine whether satisfaction and health-related quality of life (HR-QoL) differ between women who do and do not undergo contralateral prophylactic mastectomy (CPM) in the setting of implant reconstruction using the BREAST-Q, a validated patient-reported outcome instrument.

Methods. From 2000 to 2007, a total of 3,874 patients with stage 0 to III unilateral breast cancer (BC) had mastectomy; 688 (18 %) pursued CPM within 1 year. Patients who completed the BREAST-Q reconstruction module as part of BREAST-Q validation studies or routine clinical care formed our study cohort. Comparisons were made between CPM and no-CPM patients using univariate analysis and multivariate models (MVA).

Results. Of 294 patients with BREAST-Q data, 112 (38 %) had CPM. Median time from mastectomy to BREAST-Q was 52 months. CPM patients were younger (mean 47 vs. 50 years), more likely to be White (98 vs. 86 %), married (84 vs. 71 %), have a family history of BC (60 vs. 44 %), and to choose silicone implants (67 vs. 48 %). There were no differences in tumor or treatment characteristics between groups at the time of BREAST-Q. Patients with CPM had a higher mean score for Satisfaction with Breasts (64.4 vs. 54.9; $p < 0.001$) and Satisfaction with Outcome (74.8 vs. 67.7; $p = 0.007$); other HR-QoL domains did not differ. On MVA, CPM and the absence of lymphedema were significant predictors of Satisfaction with Breasts (CPM $p = 0.005$, lymphedema $p = 0.039$). CPM was not associated with improved Satisfaction with Outcome.

Conclusions. This study suggests that in the setting of implant reconstruction, CPM has a positive correlation with patient satisfaction with their breasts, but not with improvements in other HR-QoL domains.

The rate of contralateral prophylactic mastectomy (CPM) in the United States has risen significantly.[1–4] Previous studies have associated CPM with young age, White race, family history of breast cancer (BC), and treatment factors such as immediate reconstruction, preoperative magnetic resonance imaging, and unsuccessful attempts at breast conservation.[1,2,5–8] Although it has been suggested that surgeon preference may bias patients toward or against CPM, patient desire for peace of mind likely also plays a pivotal role in the decision-making process.[7,9,10] However, CPM is not without negative sequelae, which can include discontent with body image as well as diminished sexual relationships and feelings of femininity.[11–13] Some studies have also demonstrated regret among patients who have undergone prophylactic breast surgery.[14,15] With an increasing number of BC patients pursuing this option, understanding the impact of CPM on a woman's quality of life is essential.

Several studies have reported satisfaction rates after prophylactic breast surgery, with differing results.[11–14,16,17] However, none of these studies used a validated, condition-specific outcome measure to assess satisfaction. Furthermore, comparisons were made between populations with clear differences, e.g., women having prophylactic bilateral

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mastectomies versus those having CPM after a diagnosis of cancer, and women with breast reconstruction versus without. Thus, it remains unclear whether women diagnosed with BC who elect to undergo CPM are more satisfied with their breasts than women who undergo unilateral mastectomy.

The BREAST-Q is a validated patient-reported outcome (PRO) instrument specifically designed to quantify a patient's experience in terms of postsurgical satisfaction and health-related quality of life (HR-QoL) after breast surgery and reconstruction.[18] The BREAST-Q consists of 4 procedure-specific modules (augmentation, reduction, reconstruction, and mastectomy only) with independent scales that examine those issues most important to women who have undergone each procedure. It is used to provide essential information about the impact and effectiveness of breast surgery from the patient's perspective.

Previously, we reported factors associated with CPM in a large cohort of women with unilateral primary BC.[5] Here we use the BREAST-Q to compare long-term patient-reported satisfaction in a similar cohort of women with unilateral BC who did and did not pursue CPM with implant reconstruction (IR).

MATERIALS AND METHODS

Data Acquisition and Patient Selection

With institutional review board approval, institutional databases were retrospectively reviewed from January 1, 2000, to December 31, 2007, to identify patients with stage 0 to III primary unilateral BC who underwent mastectomy with or without CPM within 1 year of treatment at Memorial Sloan-Kettering Cancer Center (MSKCC). This population was then cross-referenced with a prospective database of patients who completed the satisfaction and quality-of-life scales of the postoperative BREAST-Q reconstruction module from May 2008 to May 2012 as part of BREAST-Q validation studies and routine clinical care.[19] Previous studies have demonstrated a satisfaction difference between implant-based and autologous tissue–based reconstruction, and at MSKCC, the majority of women (85 %) undergoing CPM have immediate IR.[5,17,20–22] Thus, we limited our cohort to only implant-based reconstruction. Patients with a history of BC or metastatic disease, and those receiving neoadjuvant chemotherapy, were also excluded. Patient demographics and clinical information were abstracted from the medical record.

BREAST-Q PRO Instrument

The BREAST-Q was developed at MSKCC and the University of British Columbia.[18,23,24] From 2008 to 2010, the BREAST-Q questionnaire was validated at MSKCC; it transitioned into routine clinical care in 2011.[19,25] Data from the breast reconstruction module of the BREAST-Q were used for this analysis.

The BREAST-Q reconstruction module is divided into multiple independent scales. The scales used in this study were as follows: (1) Satisfaction with Breasts—a 16-item body image scale that addresses issues such as Satisfaction with Breast shape, symmetry, feel to the touch, and appearance clothed or unclothed; (2) Satisfaction with Outcome—a 7-item scale that measures a woman's overall appraisal of her breast surgery outcome, including whether her expectations were met, the impact of surgery on her life, and the decision to have reconstructive surgery; (3) Psychosocial Well-Being—a 10-item scale that asks women to rate their confidence in a social setting, and how normal or equal to other women they feel; (4) Physical Well-Being—a 16-item scale on how often women experience pain or discomfort in the breast area and upper body; and (5) Sexual Well-Being—a 6-item scale that addresses the impact of a woman's breast condition and surgery on her sex life. Item responses for each scale are summed and transformed to provide a score ranging from 0 to 100. Higher scores indicate greater satisfaction or quality of life. Psychometric evaluation of the scales has demonstrated high levels of internal consistency and test–retest reliability (Cronbach α 0.96; intraclass correlation coefficient 0.96).[18]

Statistical Analysis

Comparisons between CPM and no-CPM patients were made by Student's t test for continuous variables, and chi-square or Fisher's exact test for categorical variables. BREAST-Q scores were compared as a continuous variable. Multivariate linear regression models (MVA) were constructed to identify independent predictors of satisfaction. All analyses are based on complete data. All p-values were two-tailed, and values of $p \leq 0.05$ were considered significant. All statistical analyses were completed by SPSS v.20.0 software (IBM, Armonk, NY).

RESULTS

From 2000 to 2007, a total of 3,874 patients with stage 0 to III primary unilateral BC underwent mastectomy; 688 (18 %) pursued CPM within 1 year of treatment. In total, 294 patients with immediate IR completed the BREAST-Q, including 112 (38 %) who had CPM (Fig. 1). From 2008 to 2010, a total of 166 patients completed the BREAST-Q as part of the validation; the remaining 128 patients completed the BREAST-Q as part of routine clinical care (2011–2012).

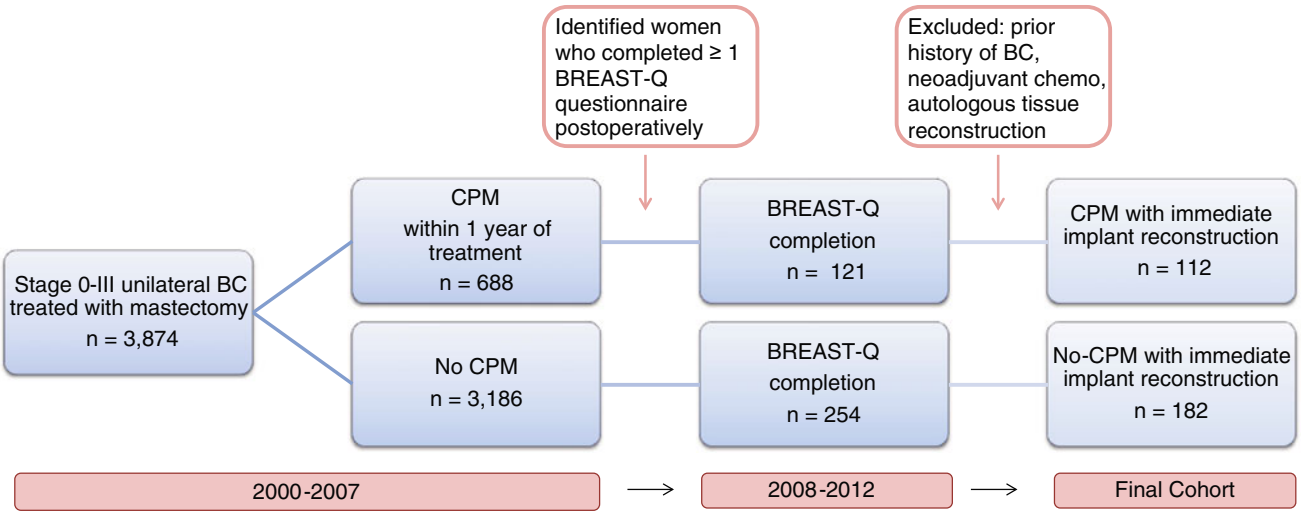

FIG. 1 Patient selection. *BC* breast cancer, *CPM* contralateral prophylactic mastectomy

The CPM group with IR and BREAST-Q data is representative of our institution's larger CPM cohort. Characteristics of the CPM group with BREAST-Q data did not differ from our previously published CPM population ($n = 407$) treated between 1997 and 2005.[5] The no-CPM group with BREAST-Q data was younger (mean 50.2 vs. 54.7 years), more likely to undergo genetic testing (18 vs. 10 %), and less likely to have invasive histology (80 vs. 87 %) than our previously published no-CPM cohort.[5] These differences are likely due to our limiting the current study to those having immediate IR and the greater availability of genetic testing in the more recent time period.

Comparing Women With and Without CPM

Patient characteristics and risk factors are summarized in Table 1. Women choosing CPM were younger (mean 47 vs. 50 years; $p = 0.001$), more likely to be White (98.2 vs. 86.3 %; $p = 0.001$), married (83.9 vs. 71.4 %; $p = 0.015$), and to have a family history of breast cancer (59.8 vs. 44.4 %; $p = 0.011$). Four patients (3.6 %) in the CPM group had a history of mantle radiotherapy. Patients in the CPM group were also more likely to undergo genetic testing (30.4 vs. 17.6 %; $p = 0.011$) and harbor a *BRCA1/2* mutation (29.4 vs. 3.2 % of those tested; $p = 0.005$).

Clinical and reconstructive factors are summarized in Table 2. There were no differences in the frequencies of invasive cancer, node positivity, estrogen receptor, progesterone receptor, HER2/neu status, or index tumor size between the CPM and no-CPM groups. Additionally, receipt of adjuvant treatment did not differ between groups. Among patients undergoing CPM, 67 % had silicone IR compared with 48 % in the no-CPM group. Forty-eight patients (42.9 %) in the CPM group elected to undergo nipple reconstruction compared to 63 (34.6 %) in the no-CPM group. A procedure for contralateral breast symmetry was performed for 60 % of patients in the no-CPM group. Minor and major complication rates, as well as rates of lymphedema and capsular contracture, did not differ between groups.

Outcomes

Median time from mastectomy to BREAST-Q completion in the CPM and no-CPM groups was 51.9 and 52.7 months, respectively. At the time of survey completion, 5 CPM group patients (4.5 %) had developed a recurrence (3 locoregional, 2 distant metastases) compared to 8 (4.4 %) no-CPM group patients (2 locoregional, 6 distant metastases). One (0.5 %) no-CPM group patient developed contralateral ductal carcinoma-in-situ 5.6 years after mastectomy for her primary BC, and no contralateral breast cancer (CBC) events occurred in the CPM group.

BREAST-Q Results

Mean BREAST-Q scores were compared for patients with and without CPM (Table 3). Patients having CPM had a significantly higher mean score for Satisfaction with Breasts (64.4 vs. 54.9; $p < 0.001$) and Satisfaction with Outcome (74.8 vs. 67.7; $p = 0.007$) 4.3 years after mastectomy; other HR-QoL domains did not differ. Linear regression was used to adjust for factors determined to differ between groups on univariate analysis (race, menopausal status, marital status, family history of BC, type of implant) as well as other factors with the potential to impact Satisfaction with Outcome (invasive histology, axillary lymph node dissection, nipple reconstruction, radiotherapy, capsular contracture, lymphedema, time from

TABLE 1 Patient characteristics

Variable	CPM ($n = 112$)		No CPM ($n = 182$)		p
Age at mastectomy, years					0.001*
Mean	46.6		50.2		
Range	33–75		23–76		
BMI, kg/m^2					0.771
Mean	24.3		24.4		
Range	16.0–47.5		17.5–36.8		
Menopausal status					0.006*
Premenopausal	84	75.0 %	108	59.3 %	
Postmenopausal	28	25.0 %	74	40.7 %	
Ethnicity					0.001*
White	109	98.2 %	157	86.3 %	
Non-White/Hispanic	2	1.8 %	25	13.7 %	
Data not available	1		0		
Marital status					0.015*
Married	94	83.9 %	130	71.4 %	
Unmarried	18	16.1 %	52	28.6 %	
Employment					0.411
Employed outside the home	83	74.8 %	128	70.3 %	
Not employed outside the home	28	25.2 %	54	29.7 %	
Data not available	1		0		
Smoking status					0.806
Smoker	6	5.4 %	11	6.0 %	
Non-smoker	106	96.4 %	171	94.0 %	
History of other cancer					0.892
Yes	11	9.8 %	17	9.3 %	
No	101	90.2 %	165	90.7 %	
History of mantle radiotherapy					0.020*
Yes	4	3.6 %	0	0 %	
No	108	96.4 %	182	100 %	
Family history of BC					0.011*
Yes	67	59.8 %	80	44.4 %	
No	45	40.2 %	100	55.6 %	
Data not available	0		2		
No. of first-degree relatives with BC					0.004*
0	74	66.1 %	146	81.1 %	
≥1	38	33.9 %	34	18.9 %	
Data not available	0		2		
No. of second-degree relatives with BC					0.165
0	65	58.0 %	119	66.1 %	
≥1	47	42.0 %	61	33.9 %	
Data not available	0		2		
Mutation carrier (of tested)					0.005*
Yes	10	29.4 %	1	3.2 %	
No	24	70.6 %	30	96.8 %	
Data not available	0		1		

CPM contralateral prophylactic mastectomy, *BMI* body mass index, *BC* breast cancer

* Statistically significant

mastectomy to BREAST-Q). On MVA, CPM and the absence of lymphedema were the only independent predictors of Satisfaction with Breasts (Table 4). The absence of lymphedema and having nipple reconstruction were independent predictors of Satisfaction with Outcome. CPM was not associated with improved Satisfaction with Outcome ($p = 0.097$).

DISCUSSION

Despite the lack of proven benefit in BC outcomes for the majority of women having CPM, an increasing number of women continue to pursue this option.[1–4,26] The decision to pursue CPM is multifactorial, and in the context of shared medical decision making, patients need meaningful data with which to make informed choices, including data on how CPM impacts quality of life. In the present study, tumor and treatment characteristics did not differ between the groups, but women electing CPM were younger and were more likely to be White, married, have a family history of BC, and harbor a *BRCA* mutation—findings consistent with prior studies. Our study adds to the growing body of literature on CPM, demonstrating that at a median of 4.3 years after surgery, using a validated PRO instrument, women having CPM in the setting of IR were significantly more satisfied with their breasts.

Previous studies have reported conflicting results regarding satisfaction after prophylactic mastectomy. Frost et al.[13] surveyed a group of women who underwent CPM from 1960 to 1993 using single-item ordinal scales for satisfaction; they found that while 92 % of respondents would choose CPM again, 45 % reported adverse effects of CPM for one or more psychological/social aspects. Geiger et al.[16] surveyed 519 women who had CPM from 1979 to 1999 and a much smaller subset of women who did not ($n = 61$). Using a 5-point scale, there was no difference between the groups with regard to quality of life contentment ($p = 0.218$). There was also no difference in other 2-point scales, including self-consciousness about appearance, satisfaction with appearance when dressed, or satisfaction with sex life. These studies relied on ad hoc and generic instruments, which have been proven relatively unreliable and insensitive to the unique issues of breast surgery/reconstruction.[27] In contrast, the BREAST-Q is a validated, reliable, and responsive outcome measure that evaluates the patient experience specifically related to breast surgery. In our study, the two BREAST-Q scales with differences in raw score between patients with and without CPM were Satisfaction with Breasts and Satisfaction with Outcome. Women who elected CPM scored significantly higher on Satisfaction with Breasts.

TABLE 2 Clinical factors and reconstructive factors

Variable	CPM ($n = 112$)		No CPM ($n = 182$)		p
Clinical factors					
Invasive cancer	82	73.2 %	145	79.7 %	0.200
Tumor size, cm (range)					0.199
Median	1.4		1.5		
Range	0.0–5.0		0.1–11.0		
Nodal status					0.192
Negative	43	52.4 %	63	43.4 %	
Positive	39	47.6 %	82	56.6 %	
ER					0.549
Negative	17	21.8 %	26	18.4 %	
Positive	61	78.2 %	115	81.6 %	
Data not available	4		4		
PR					0.480
Negative	24	31.2 %	51	35.9 %	
Positive	53	68.8 %	91	64.1 %	
Data not available	5		3		
HER2/neu (IHC and FISH)					0.997
Negative	62	81.6 %	115	81.6 %	
Positive	14	18.4 %	26	18.4 %	
Data not available	6		4		
Adjuvant chemotherapy					0.526
Yes	66	58.9 %	114	62.6 %	
No	46	41.1 %	68	37.4 %	
Hormone therapy					0.086
Yes	64	57.7 %	123	67.6 %	
No	47	42.3 %	59	32.4 %	
Data not available	1		0		
Radiotherapy					0.312
Yes	26	23.2 %	52	28.6 %	
No	86	76.8 %	130	71.4 %	
Reconstructive factors					
Silicone implant (at BREAST-Q)	75	67.0 %	87	47.8 %	0.001*
Nipple reconstruction	48	42.9 %	63	34.6 %	0.157
Type of nipple reconstruction					0.354
Local advancement flap	20	42.6 %	21	33.9 %	
Full thickness skin graft	27	57.4 %	41	66.1 %	
Data not available	1		1		
Contralateral symmetry procedure			110	60.4 %	
Complications					0.406
Minor (scarring, delayed wound healing, fat necrosis, failed nipple reconstruction)	15	13.4 %	20	11.0 %	
Major (IV antibiotics, implant replacement, return to OR)	22	19.6 %	27	14.8 %	
Lymphedema	8	7.1 %	19	10.4 %	0.342
Capsular contracture	36	32.1 %	70	38.5 %	0.273

CPM contralateral prophylactic mastectomy, *ER* estrogen receptor, *PR* progesterone receptor, *IV* intravenous, *OR* operating room

* Statistically significant

Previous studies have demonstrated that satisfaction with IR declines with time; women happy with their initial outcome are less satisfied when surveyed later.[28–30] This may be partly due to the occurrence of capsular contractures. In our cohort, the capsular contracture rate was not different between groups; however, natural changes in the contralateral breast over time may have contributed to differences in symmetry, resulting in decreased satisfaction in the no-CPM group. Although 60 % of women in the no-CPM group elected to have a contralateral symmetry procedure, changes in weight and increasing ptosis of the contralateral breast over time make it difficult to sustain long-term symmetry. This may partly explain why women who elected CPM and IR were more satisfied with their breasts compared to women with unilateral mastectomy and IR. It also highlights the importance of providing realistic expectations regarding changes in breast contour over time to women undergoing unilateral mastectomy.

Silicone IR was pursued in 67 % of CPM patients versus 47.8 % of women in the no-CPM group. In previous studies that used the BREAST-Q, both McCarthy et al.[28] and Macadam et al.[31] demonstrated that in the setting of postmastectomy reconstruction, patients who chose silicone breast implants reported significantly higher

TABLE 3 Comparisons of BREAST-Q score by scale: CPM versus no CPM

BREAST-Q scales	No. completing	Mean score (range 0–100)	SD	Mean score difference[a]	p
Satisfaction with Breasts					
CPM	112	64.4	15.8	9.5	<0.001*
No CPM	182	54.9	20.3		
Satisfaction with Outcome					
CPM	112	74.8	20.3	7.1	0.007*
No CPM	180	67.7	22.2		
Psychosocial well-being					
CPM	112	75.4	19.8	3.1	0.232
No CPM	182	72.3	22.3		
Physical well-being, chest					
CPM	111	77.4	15.6	2.4	0.228
No CPM	179	75.0	17.5		
Sexual well-being					
CPM	111	55.1	22.9	2.8	0.327
No CPM	175	52.3	23.1		

CPM contralateral prophylactic mastectomy, *SD* standard deviation

* Statistically significant

[a] Unadjusted scores

TABLE 4 Multivariate analyses for predictors of Satisfaction with Breasts and Satisfaction with Outcome

Variable	Satisfaction with Breasts			Satisfaction with Outcome		
	Δ in BREAST-Q score (β)	95 % CI	*p*	Δ in BREAST-Q score (β)	95 % CI	*p*
CPM	6.8	2.1 to 11.5	0.005*	4.6	−0.8 to 10.0	0.097
White	7.3	−0.7 to 15.2	0.074	−0.8	−10.0 to 8.4	0.871
Postmenopausal	−3.5	−8.1 to 1.2	0.140	−4.6	−10.0 to 0.7	0.090
Married	0.3	−5.1 to 5.7	0.914	0.9	−5.3 to 7.1	0.782
Family history of breast cancer	−2.6	−7.0 to 1.8	0.246	−0.9	−5.9 to 4.2	0.735
Invasive cancer vs. DCIS	−5.3	−11.0 to 0.3	0.065	−4.4	−10.9 to 2.2	0.191
Axillary lymph node dissection	−2.9	−8.8 to 3.0	0.327	−1.2	−8.0 to 5.6	0.728
Silicone vs saline implant	3.1	−1.4 to 7.6	0.176	2.6	−2.6 to 7.8	0.326
Nipple reconstruction	1.8	−2.9 to 6.6	0.451	7.9	2.4 to 13.4	0.005*
Radiotherapy	0.2	−6.9 to 7.2	0.965	3.2	−4.9 to 11.3	0.435
Capsular contracture	−2.8	−7.8 to 2.3	0.280	−1.4	−7.2 to 4.4	0.631
Lymphedema	−8.5	−16.6 to −0.4	0.039*	−9.8	−19.1 to −0.5	0.039*
Months from mastectomy to BREAST-Q	0.1	−0.1 to 0.2	0.399	0.1	−0.1 to 0.2	0.497

Δ change, *β* beta coefficient, *CI* confidence interval, *CPM* contralateral prophylactic mastectomy, *DCIS* ductal carcinoma-in-situ

* Statistically significant

Satisfaction with Breasts than those who chose saline implants, and that a proportional negative affect was also observed in patients receiving radiotherapy. Because of this difference, both type of implant and receipt of radiotherapy were included in the MVA in this study, and were not significant. Nipple reconstruction also did not correlate significantly with Satisfaction with Breasts, but it did have a positive correlation with satisfaction with overall outcome.

Satisfaction with Outcome measures a woman's overall appraisal of her breast surgery outcome. Although CPM patients had a higher mean raw score for Satisfaction with Outcome, CPM was not an independent predictor of Satisfaction with Outcome on MVA. In this study, both groups of women underwent therapeutic mastectomy for a diagnosis of BC and thus shared the common experience of surviving cancer. As other studies have suggested, this experience can translate into a better appreciation of life and sense of renewal, which may partly explain the similar satisfaction with overall outcome.[12,16]

Major and minor complications occurred at the same rate in both groups. Eight patients (7.1 %) in the CPM group and 19 patients (10.4 %) in the unilateral mastectomy group developed lymphedema. On MVA, lymphedema correlated negatively with Satisfaction with Breasts and Satisfaction with Outcome, which is consistent with other reports that lymphedema is a risk factor for decreased satisfaction after BC surgery.[32–34] Furthermore, other clinical factors, such as patient age, race, and body mass index, have been demonstrated to influence or confound HR-QoL outcomes among patients with BC-related lymphedema.[35]

Locoregional and distant metastatic disease rates did not differ between the groups, with only one patient in the no-CPM group developing CBC. Many women overestimate their risk of developing CBC.[36,37] Thus, clinicians should stress the low risk of CBC and the lack of proven survival benefit when counseling patients on the benefits of CPM, and they should highlight the same long-term overall Satisfaction with Outcome regardless of decision to pursue CPM.

The current study is particularly relevant because it is restricted to the modern surgical and reconstructive era. Others have reported patient satisfaction over several decades of surgical treatment, during which great advances in reconstructive techniques occurred. A limitation of this study is the inability to control for systematic differences in patient characteristics, such as risk adversity and/or personality traits. Patients who choose CPM may systematically differ from those who do not, which may be reflected in their BREAST-Q responses. By adjusting for a large number of measurable variables, we have attempted to control for such differences. Additionally, survey response rate plays a role in selection bias; patients who were extremely satisfied or not at all satisfied may be more apt to respond to the survey.

In summary, the BREAST-Q enabled us to capture essential information regarding the impact of CPM on patient satisfaction. These data suggest that in the setting of IR, CPM has a positive correlation with long-term patient satisfaction with their breasts. However, satisfaction with overall outcome was not predicted by a woman's choice regarding CPM. In the context of shared medical decision

making, patients need meaningful data with which to make informed choices regarding CPM. As physicians, it is essential for us to allow patients time to come to a decision and to set appropriate postoperative expectations.

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DISCLOSURE The BREAST-Q is owned by Memorial Sloan-Kettering Cancer Center and the University of British Columbia. Dr. Pusic is a codeveloper of the BREAST-Q and receives a share of licensing revenues based on the inventor sharing policies of these two institutions. The other authors declare no conflict of interest.

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