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## A Comparison of Patient-Reported Outcomes After Breast-Conserving Surgery and Mastectomy with Implant Breast Reconstruction

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## Abstract

**Background**—Many factors influence decisions regarding choice of breast-conserving surgery (BCS) versus mastectomy with reconstruction for early invasive breast cancer. The purpose of this study was to compare patient satisfaction following BCS and mastectomy with implant reconstruction (M-iR) utilizing the BREAST-Q patient-reported outcome measure.

**Methods**—Women with stage I or II breast cancer undergoing BCS or M-iR who completed a BREAST-Q from 2010 to 2016 were identified by retrospective review of a prospective database. Baseline characteristics were compared, and linear mixed models were used to analyze associations with BREAST-Q scores over time.

**Results**—Our study group was composed of 3233 women; 2026 (63%) had BCS, 123 (3.8%) had nipple-sparing mastectomy, and 1084 (34%) had skin-sparing or total mastectomy. Median time from surgery to BREAST-Q was 205 days for BCS and 639 days for M-iR (p<0.001). Regardless of type of surgery, breast satisfaction scores decreased significantly over time (p<0.001), whereas psychosocial (p=0.001) and sexual (p=0.004) well-being scores increased significantly over time. BCS was associated with significantly higher scores over time as compared with M-iR across all subscales (all p<0.001). Radiation was significantly associated with decreased scores over time across all subscales (all p<0.05).

**Conclusions**—Breast satisfaction and quality-of-life scores were higher for BCS compared to M-iR in early-stage invasive breast cancer. These findings may help in counseling women who have a choice for surgical treatment. Breast satisfaction scores decreased over time in all women, highlighting the need for further evaluation with longer follow-up.

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## Synopsis:

Breast satisfaction and quality-of-life scores are higher for breast-conserving surgery compared to mastectomy with implant reconstruction in early-stage invasive breast cancer.

#### **Keywords**

breast cancer; patient-reported outcomes; breast-conservation surgery; mastectomy; breast reconstruction; BREAST-Q

## INTRODUCTION

Women with early-stage invasive breast cancer often have a choice of surgical procedure breast-conserving surgery (BCS) followed by adjuvant radiation versus mastectomy with or without reconstruction. Multiple prospective randomized trials have demonstrated equivalent survival,<sup>1</sup> and local recurrence rates after BCS are now similar to mastectomy.<sup>2,3</sup> Despite increased complication rates<sup>4,5</sup> and no difference in survival, the odds of mastectomy with reconstruction in BCS-eligible women in the U.S. increased 34% between 2003–2011.<sup>6</sup> The rise between 2005 and 2011 reflects an increase in contralateral prophylactic mastectomy (CPM) from 54 to 118 per thousand cases of early breast cancer.<sup>7</sup> It has been suggested that this increase is at least partially attributed to improved access to reconstructive procedures, <sup>7,8</sup> with the largest increase being mastectomy followed by implant-based reconstruction (M-iR).<sup>9</sup>

It is imperative for patients and providers to understand satisfaction with surgical outcomes and quality of life (QOL) in both the short- and long-term to make informed decisions regarding surgical management. Studies have demonstrated the superiority of autologous over implant-based reconstruction,<sup>10</sup> as well as greater satisfaction with breasts among women who chose CPM with implant reconstructions than among women with unilateral reconstructions.<sup>11</sup> However, there are less contemporary data comparing BCS and mastectomy. A retrospective cross-sectional study of over 7000 patients evaluated breast satisfaction at a single time point after surgery among women with a self-reported history of breast cancer, but did not assess additional QOL measures.<sup>12</sup>

The purpose of this study was to compare breast satisfaction, and psychosocial and sexual well-being subscales of the BREAST-Q, a validated patient-reported outcomes measure, among women who underwent BCS or mastectomy with implant reconstruction (M-iR) among women with early-stage invasive breast cancer.

## METHODS

We performed a retrospective review using a prospectively maintained database of women who underwent BCS or M-iR between 2010–2016 at Memorial Sloan Kettering Cancer Center (MSK). Women were eligible for study inclusion if they had stage I or II invasive breast cancer and completed at least one postoperative BREAST-Q survey. Approval was obtained from the MSK Institutional Review Board.

The BREAST-Q is a validated patient-reported outcome measure of breast-related satisfaction and QOL.<sup>13–15</sup> Both the mastectomy-with-reconstruction and breast-conservation modules contain three QOL and three satisfaction domains. The QOL domains are physical, psychosocial, and sexual well-being; the satisfaction domains are satisfaction with breasts, outcome, and care. The breast-conservation module has an additional component addressing the side effects of radiation. Each module has preoperative and postoperative versions. For this study, we focused on the shared modules of psychosocial well-being, sexual well-being, and satisfaction with breasts. Domain scores were obtained by transforming scaled responses into a range from 0–100, with higher scores indicating greater satisfaction or QOL. BREAST-Q surveys were distributed to patients immediately postoperatively (within 1 month), and then every 6 months thereafter. Therefore, each patient may have completed a different number of BREAST-Q surveys based on the time since her surgical date and preference for filling out the survey.

The decision to perform breast conservation or mastectomy was made at the discretion of the patient, breast surgical oncologist, and plastic surgeon. Mastectomy included both skin-sparing and nipple-sparing mastectomy, and these were categorized together given previous data from our institution showing no difference in satisfaction or QOL.<sup>16</sup> Only implant-based reconstruction was evaluated given the small number of patients with autologous reconstruction who had BREAST-Q scores during this time period.

The primary outcome of interest was BREAST-Q score over time. Demographic variables included age, race, and marital status. Clinical characteristics common to all patients included year of surgery, body mass index (BMI), histology of invasive cancer, pathologic stage, laterality, performance of an axillary procedure, and receipt of chemotherapy and/or radiation. Breast-conservation-specific variables included conversion from breast conservation to mastectomy and number of re-excisions. Mastectomy-specific variables included contralateral prophylactic mastectomy. Axillary procedures included both sentinel lymph node biopsy and axillary lymph node dissection. Receipt of radiation and chemotherapy were considered as binary variables.

Continuous variables were summarized using median and range, and categorical variables were summarized using frequency and percentage. Comparisons across surgery type were made using the Wilcoxon rank-sum test for continuous variables, and Fisher's exact test or the Chi-squared test, as appropriate, for categorical variables. Linear mixed effects models were used to analyze associations with BREAST-Q scores over follow-up time, incorporating a random intercept and slope for each patient to account for the correlation among scores from an individual patient over time. Multivariable mixed effects models adjusted for factors that were significant on univariable analysis. For continuous predictors, the provided estimates represent the average difference in score over time for a one-unit increase in the predictor (e.g., one year of age). For categorical predictors, the provided estimates represent the average difference in score over time for the specified level of the predictor of interest compared to the reference group. Sensitivity analyses were performed to evaluate stage I patients only.

A p-value <0.05 was considered statistically significant. All statistical analyses were conducted in R version 3.5.0 (R Core Development Team, Vienna, Austria, 2018).

## RESULTS

## **Patient Characteristics**

During the study period, 3233 women completed at least one postoperative BREAST-Q survey. The median number of surveys completed for both BCS and M-iR was 2 (1–6). The majority of patients underwent BCS (2026, 63%), followed by total (1084, 34%) and nipple-sparing (123, 3.8%) mastectomy with implant-based reconstruction. Patient demographic, tumor, and treatment characteristics are detailed in Table 1. M-iR patients were younger, more often married, had lower BMI, and more frequently had bilateral and axillary surgeries, had stage II versus I disease, and received chemotherapy. BCS patients more frequently received radiation. The majority of BCS patients had a single surgical procedure (79%), and 90 (2.8%) patients converted from BCS to M-iR.

#### BREAST-Q Scores

The median time from surgery to BREAST-Q completion was 382 days (range 1–2746). Time to BREAST-Q completion was significantly longer for M-iR patients (639 days, range 27–2746) than for BCS patients (205 days, range 1–2206)(Fig. 1). The median number of postoperative BREAST-Q surveys per patient was 5 (range 1–18); this was significantly greater for M-iR patients (6, range 1–9) compared to BCS patients (4, range 1–18)(p<0.001).

For all subscales, BREAST-Q scores were higher over time among BCS compared to M-iR patients. On univariable analysis, breast satisfaction scores decreased significantly over time (p<0.001) independent of surgery type, whereas psychosocial (p=0.001) and sexual (p=0.004) well-being scores increased significantly over time (Fig. 2).

On multivariable analysis, breast satisfaction, psychosocial well-being scores, and sexual well-being scores all remained significantly lower for M-iR compared to BCS over time (Table 2). Receipt of radiation was significantly associated with lower scores in all domains, regardless of surgery type. Breast satisfaction scores were significantly worse with increasing days from surgery, older age, and pathologic stage II versus I patients. Psychosocial well-being scores were significantly lower for pathologic stage II versus I patients. Sexual well-being scores were significantly lower for patients who received chemotherapy.

#### Sensitivity Analysis of Stage I Patients

A sensitivity analysis was performed among women most likely to have a choice of surgical procedure due to small invasive tumor size (stage I only). Each of the three scores was significantly lower for patients who underwent M-iR compared to BCS (breast satisfaction: Estimate -16.932, standard error (SE) 1.390, p<0.001; psychosocial well-being: Estimate -9.211, SE 1.391, p<0.001; sexual well-being: Estimate -12.024, SE 1.756, p<0.001).

## DISCUSSION

Breast-conserving surgical techniques were developed to improve cosmetic outcome and physical function for women undergoing surgery for breast cancer. BCS results in similar locoregional recurrence rates and equivalent survival to mastectomy, yet between 2005–2011 rates of BCS declined by 2% per year.<sup>7</sup> In contrast, despite declining contralateral breast cancer rates<sup>17</sup> and only a small proportion of women with high-risk genetic mutations, rates of bilateral mastectomy for unilateral breast cancer are increasing.<sup>6,7,18</sup> The reasons for this are multifactorial, and include patient choice and availability of reconstructive services.<sup>7,19</sup> For physicians counseling women during the surgical decision-making process, and for women attempting to make informed decisions based on their values and priorities, it is important to have evidence-based information on patient satisfaction and QOL pertaining to each type of surgical procedure.

To our knowledge, this study represents the largest sample of prospectively collected BREAST-Q surveys comparing BCS and M-iR outcomes over time. We found that regardless of patient, clinical, and treatment variables, BCS patients scored higher in all domains evaluated over time compared to M-iR patients. Only two previous studies have compared BCS and mastectomy using the BREAST-Q. The larger of these, by Atisha et al., recruited adult women who had undergone breast cancer treatment within the prior 20 years from the Army of Women program.<sup>12</sup> Over 7000 women provided self-reported cancer data from a single post-treatment time point and completed the breast-satisfaction module of the BREAST-Q questionnaire. Similar to our study, implant-based reconstruction scored significantly lower than BCS. The second study, by Howes et al., found higher breast satisfaction, psychosocial well-being, and sexual well-being associated with mastectomy compared to BCS, but the reconstruction types were not reported.<sup>20</sup> If the majority of reconstructions were autologous, this would align with numerous other studies indicating increased patient satisfaction with autologous compared to implant-based reconstruction. <sup>10,21–23</sup> Interestingly, Howes et al. included a control group of 123 women without a history of breast surgery or breast cancer, and found no statistically significant difference in breast satisfaction scores compared to those who underwent BCS. This suggests that in women without a contraindication to BCS, mastectomy and reconstruction are likely not necessary to obtain an acceptable and durable cosmetic result. Additionally, there is some evidence that with the movement toward oncoplastic approaches, BCS outcomes may continue to improve.<sup>24</sup> This is being evaluated in a prospective cohort study investigating OOL and cosmetic result satisfaction in women with breast cancer undergoing standard lumpectomy versus level I or II oncoplastic BCS.25

Sexual function is a primary concern among cancer survivors not often addressed in the preoperative setting, despite its importance to patients. In 2006 the Livestrong Foundation conducted a large survey of adult cancer survivors, including over 700 with breast cancer, to better understand survivors' needs after treatment completion. Almost half of survey respondents (46%) indicated experience of concern with sexual functioning.<sup>26</sup> Our study shows that the impact of surgical treatment on sexual functioning is associated with surgery type. Although scores in both groups increased over time, women who underwent BCS maintained higher sexual function at all time points compared to M-iR. Studies generally

show sexual activity and function improving over time after breast cancer treatment,<sup>27,28</sup> but the effect of surgery is inconsistent. One case-control study of 149 women with breast cancer and 149 age-matched healthy controls found that at one year postoperatively, women who underwent mastectomy reported problems with sexual desire, arousal, and the ability to achieve an orgasm.<sup>27</sup> Another more-recent, cross-sectional study demonstrated higher breast-specific sensuality scores for BCS compared to mastectomy patients, but did not find this translated to overall improved Female Sexual Function Index scores.<sup>29</sup> A prospective cohort study of 258 women with breast cancer treated at The University of Texas MD Anderson Cancer Center demonstrated pleasure from sexual activity significantly increased over time at 12 and 24 months of follow-up, with no differences according to surgical treatment.<sup>28</sup> Findings in our study also indicate that chemotherapy receipt is an independent predictor of poor sexual function over time, which is supported in the literature.<sup>30–32</sup> Most patients do not seek treatment for sexual dysfunction after breast cancer treatment, but these data provide an opportunity to counsel patients about future expectations or to help develop programs that can support this aspect of survivorship.

Our study findings confirmed other reports<sup>22,33</sup> demonstrating radiation as an independent predictor of poor patient-reported outcomes. Our study showed decreased breast satisfaction, psychosocial well-being, and sexual well-being over time associated with radiation. Women undergoing BCS have reported changes with breast fibrosis up to 20 years after whole-breast irradiation, and postmastectomy radiation after implant-based reconstruction is associated with capsular contracture and reconstructive failure.<sup>33-36</sup> With a mean follow-up of 3.3 years for irradiated and 3.7 years for non-irradiated patients, Albornoz et al. found that implant-based reconstruction patients who had radiation had significantly lower BREAST-Q scores across satisfaction with breasts, psychosocial well-being, and sexual well-being versus non-irradiated patients.<sup>37</sup> Similarly, in a survey including 1450 women with nonmetastatic breast cancer who underwent BCS or mastectomy with or without adjuvant radiation, Jagsi et al. found that patients who received radiation after M-iR had significantly lower satisfaction than all other subgroups, rating their overall cosmetic result as "dissatisfied" on average.<sup>22</sup> To combat some of these less-than-satisfactory cosmetic results associated with M-iR, there is increasing interest in prepectoral implants with acellular dermal matrix. One recent study found that patients with subpectoral implants experienced a three-fold greater rate of capsular contracture versus prepectoral implants after radiation (52% versus 16%).<sup>38</sup> Studies are also ongoing to determine whether shorter courses of postmastectomy radiation can maintain locoregional control but improve cosmetic outcomes.<sup>39</sup> Radiation remains an important aspect of locoregional control with survival benefits in some patients.<sup>1,40</sup> As a result, patients need to be counseled regarding both the benefits as well as the QOL drawbacks.

Time from surgery was also an important factor associated with satisfaction with breasts and QOL. Satisfaction with breasts decreased over time regardless of type of procedure, whereas sexual and psychosocial well-being improved. Consistent with our findings, Atisha et al. also reported that breast satisfaction declined over time for both BCS and M-iR.<sup>12</sup> They did find that women with autologous reconstruction had relatively stable satisfaction with breasts, and hypothesized that whereas the autologous reconstructed breast may naturally age over time with a higher degree of preserved symmetry, this may be more difficult to

attain with an implant-based reconstruction, leading to lower satisfaction over time. Most interesting is our finding that sexual and psychosocial well-being improved over time. This suggests that while there is an unfortunate decrease in satisfaction with breasts over time, there are interval gains in other important aspects of patients' lives. While these improvements may simply be reflective of the time elapsed from a breast cancer diagnosis to treatment, reinforcing for patients that their psychosocial well-being and sexual function will likely improve over time may be beneficial.

There are several limitations to our study. Our study population represents a convenience sample of patients willing to take the BREAST-Q survey and seen at a highly specialized tertiary cancer care center; biases among women who chose to seek care at our institution and participate in completing the survey that may not be generalizable to a broader population may be present. We were unable to determine eligibility for breast conservation in our study population. This may have negatively affected the scores of patients who desired breast conservation but who, due to disease extent, underwent mastectomy. Additionally, given the small number of preoperative surveys completed by BCS patients, we were unable to adjust for preoperative BREAST-Q score. This could create bias if women who underwent BCS had higher baseline scores. However, our results support previous literature with similar outcomes,<sup>12</sup> making this possibility less likely. Lastly, although we adjusted for differences in time from surgery to BREAST-Q completion among the two study groups, the relatively fewer patients with long-term follow-up in the BCS group could have produced unstable estimates, with potential for bias in either direction. Longer follow-up BREAST-Q data are currently being collected to address this issue.

#### Conclusions

Our study demonstrates that breast satisfaction, psychosocial well-being, and sexual wellbeing are all higher over time among early-stage invasive breast cancer patients undergoing BCS compared to M-iR. In an era of increasing bilateral mastectomies, the majority of which are implant-based, these data provide valuable information for counseling patients regarding their surgical options and QOL. More long-term data are needed on QOL outcomes associated with surgical management of early-stage breast cancer.

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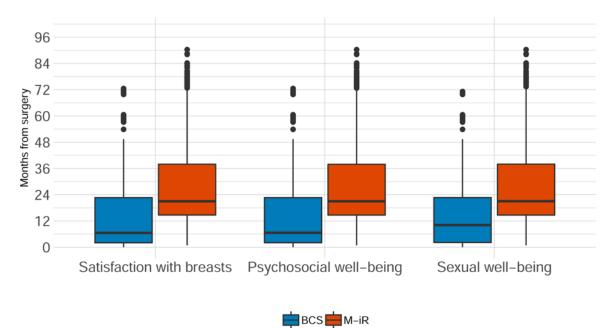
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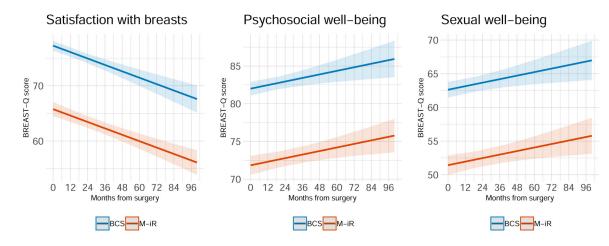
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## Fig 1.

Distribution of time from surgery to BREASTQ measurement in BCS compared to M-iR separately for each subscale and according to surgery type.

BCS breast-conserving surgery, M-iR mastectomy with implant reconstruction



#### Fig. 2.

Association between time from surgery and BREAST-Q score, separately for each subscale and according to surgery type.

BCS breast-conserving surgery, M-iR mastectomy with implant reconstruction

#### TABLE 1

Patient Demographic, Clinicopathologic, and Treatment Characteristics According to Type of Surgery

Variable	Total (n = 3233)	Breast- conserving surgery (n = 2026)	Mastectomy (n = 1207)	p-value
Age, years (median, range)	53 (23–97)	57 (26–97)	48 (23–78)	< 0.001
Year of Surgery				< 0.001
2010	224 (6.9)	124 (6.1)	100 (8.3)	
2011	343 (10.6)	135 (6.7)	208 (17.2)	
2012	493 (15.2)	264 (13)	229 (19)	
2013	606 (18.7)	395 (19.5)	211 (17.5)	
2014	603 (18.7)	420 (20.7)	183 (15.2)	
2015	594 (18.4)	412 (20.3)	182 (15.1)	
2016	370 (11.4)	276 (13.6)	94 (7.8)	
Marital status (n, %)				< 0.001
Married/partnered	2269 (70.2)	1376 (67.9)	893 (74.0)	
Divorced/separated/single/widowed	964 (29.8)	650 (32.1)	314 (26.0)	
Race (n, %)				0.6
White	2624 (81.2)	1646 (81.2)	978 (81.0)	
Other	456 (14.1)	280 (13.8)	176 (14.6)	
Did not report	153 (4.7)	100 (4.9)	53 (4.4)	
Body mass index (median, range)	25.4 (15.5–58.6)	26.2 (15.5–58.6)	24 (16–51)	< 0.001
Histology (n, %)				0.069
Invasive ductal or lobular carcinoma	3177 (98.3)	1984 (97.9)	1193 (98.8)	
Other	56 (1.7)	42 (2.1)	14 (1.2)	
Laterality (n, %)				< 0.001
Bilateral	246 (7.6)	56 (2.8) 190 (15.		
Left	1518 (47.0)	1031 (50.9)	487 (40.3)	
Right	1469 (45.4)	939 (46.3)	530 (43.9)	
Pathologic stage				< 0.001
Ι	2283 (70.6)	1486 (73.3)	797 (66.0)	
Π	950 (29.4)	540 (26.7)	410 (34.0)	
Conversion from breast conservation to mastectomy	90 (2.8)	0 (0.0)	90 (7.5)	< 0.001
Number of re-excisions				NA
0	1596 (49.4)	1596 (78.8)	0 (0.0)	
1	382 (11.8)	382 (18.9)	0 (0.0)	
2	48 (1.5)	48 (2.4)	0 (0.0)	
Not applicable	1207 (37.3)	0 (0.0)	1207 (100.0)	

Variable	Total (n = 3233)	Breast- conserving surgery (n = 2026)	Mastectomy (n = 1207)	p-value
Contralateral prophylactic mastectomy	450 (13.9)	0 (0.0)	450 (37.3)	NA
Axillary Procedure	3132 (96.9)	1957 (96.6)	1175 (97.3)	< 0.001
Chemotherapy	1523 (47.1)	905 (44.7)	618 (51.2)	< 0.001
Radiation	2140 (66.2)	1862 (91.9)	278 (23.0)	< 0.001

NA not available

### TABLE 2

Multivariable Analysis of BREAST-Q Subscale Scores (Satisfaction With Breasts, Psychosocial Well-Being, Sexual Well-Being) Comparing Mastectomy With Implant-Based Reconstruction and Breast-Conservation Surgery

	Estimate	Standard error	p-value
Breast satisfaction			
Mastectomy versus BCS	-16.067	1.082	<.001
Days from surgery	-0.003	0.000	< .001
Age	-0.161	0.031	< .001
Bilateral procedure	0.921	1.250	0.461
Axillary procedure	-2.053	2.108	0.33
Pathologic stage II versus I	-2.401	0.757	0.002
Chemotherapy	-1.120	0.713	0.116
Adjuvant radiation	-4.690	1.020	< .001
Conversion from BCS to mastectomy	1.902	1.992	0.34
Psychosocial well-being			
Mastectomy versus BCS	-10.604	1.091	<.001
Days from surgery	0.001	0.000	<.001
Age	0.105	0.032	0.001
Bilateral procedure	-0.492	1.264	0.697
Axillary procedure	-3.264	2.109	0.122
Pathologic stage II versus I	-1.670	0.766	0.029
Chemotherapy	-1.072	0.723	0.138
Adjuvant radiation	-2.395	1.033	0.02
Conversion from BCS to mastectomy	-0.756	2.004	0.706
Sexual well-being			
Mastectomy versus BCS	-13.046	1.341	<.001
Days from surgery	0.002	0.001	0.004
Age	0.030	0.042	0.464
Bilateral procedure	1.481	1.519	0.33
Axillary procedure	-0.925	3.108	0.766
Pathologic stage II versus I	-0.790	0.960	0.41
Chemotherapy	-2.557	0.903	0.005
Adjuvant radiation	-2.799	1.315	0.033
Conversion from BCS to mastectomy	0.104	2.343	0.965

BCS breast-conserving surgery