Patient Satisfaction and Health-Related Quality of Life following Breast Reconstruction: Patient-Reported Outcomes among Saline and Silicone Implant Recipients

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Background: In recent years, there has been a growing acceptance of the value of breast reconstruction. The majority of women who choose to proceed will undergo alloplastic reconstruction. The primary objective of this study was to determine whether the type of implant used in alloplastic breast reconstruction has an impact on patient-reported satisfaction and quality of life.
Methods: Patients were deemed eligible if they had completed alloplastic reconstruction at least 1 year before study initiation. Patients were contacted by mail: two questionnaires [the BREAST-Q and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (Br23) (EORTC QLQC30 (Br23))], a contact letter, and an incentive gift card were included. Scores were compared between silicone and saline implant recipients.
Results: Seventy-five silicone implant recipients and 68 saline implant recipients responded, for a response rate of 58 percent. BREAST-Q responses showed silicone implant recipients to have higher scores on all nine subscales. This difference reached statistical significance on four of nine subscales: overall satisfaction (p = 0.008), psychological well-being (p = 0.032), sexual well-being (p = 0.05), and satisfaction with surgeon (p = 0.019). Regression analysis adjusted for follow-up time, timing of surgery, unilateral versus bilateral surgery, radiation, and age. Results from the EORTC QLQC30 (Br23) showed a statistically significant difference on two of 22 subscales: silicone recipients had higher overall physical function, and saline recipients had higher systemic side effects.
Conclusions: This study has shown higher satisfaction with breast reconstruction in silicone gel implant recipients compared with saline recipients using the BREAST-Q. There was no difference in overall global health status between the two patient groups as measured by the EORTC-QLQC30 (Br23). (*Plast. Reconstr. Surg.* 125: 761, 2010.)

Breast cancer is the most common cancer among North American women.[1] Among those diagnosed, a large number will require mastectomy as part of the treatment plan.[2]

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The rate of breast reconstruction following mastectomy has historically ranged from 8 to 15 percent.[3–6] In recent years, however, there has been growing acceptance of the value of postmastectomy breast reconstruction, and rates as

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high as 40 percent have been reported.[7] Approximately one-half of women who choose to undergo reconstruction will proceed with alloplastic reconstruction.[8]

As reconstruction rates increase, so may the demand for information regarding outcomes. Ongoing research continues to address breast implant safety concerns, such as the risk of rupture and reoperation.[9–12] Many women today, however, are faced with uncertainties about the efficacy of breast implants. The choice between a saline or silicone implant may be further complicated by the media's representation of silicone-related complications.[13] Patient-reported data are therefore required to help future patients make informed decisions about the overall results of implant reconstruction, and more specifically the differences between saline and silicone implants.

Research in this field has been hindered by the absence of an outcomes measure for use in evaluation of patient satisfaction and health-related quality of life (HRQoL). Prior studies suggest an improved postsurgical body image in patients who undergo breast reconstruction.[14–17] More recently, studies have shown variable outcomes. Shover et al.[18] examined patients with a history of partial mastectomy or immediate reconstruction/mastectomy using two self-report questionnaires.[19,20] No difference was found for overall psychosocial adjustment to illness, body image, or satisfaction with sexual life. Rowland et al.[21] followed patients with a history of lumpectomy, mastectomy, and mastectomy/reconstruction using six outcomes measures.[22–27] No difference in emotional, social, or role function was found. Wilkins et al. prospectively followed patients undergoing alloplastic and transverse rectus abdominis musculocutaneous flap breast reconstruction.[28] Emotional well-being, vitality, mental health, social functioning, functional well-being, social well-being, and body image were measured using two surveys.[29,30] There were no significant effects of procedure type; however, improvements in psychosocial variables occurred for all patient groups following reconstruction.

These previous studies highlight the absence of a standardized instrument to accurately assess health-related quality of life in this patient population. A recent systematic review identified 227 patient-reported outcomes measures used in breast surgery patients.[31] The BREAST-Q is a new questionnaire that specifically measures postsurgical body image and quality of life in the breast reconstruction patient.[32–34] The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (Br23) [EORTC QLQC30 (Br23)] is a cancer-specific questionnaire that incorporates a breast-specific module and measures overall functioning following breast cancer treatment.[35–40]

To date, there have been no prior studies that have employed these questionnaires to evaluate patient satisfaction and health-related quality of life following alloplastic breast reconstruction. More specifically, it is unknown whether the type of implant used (saline versus silicone) has an effect on health-related quality of life. The aim of this study was to determine whether implant type has an effect on patient satisfaction and health-related quality of life following alloplastic breast reconstruction using the BREAST-Q and the EORTC QLQC30 (Br23) questionnaires.

PATIENTS AND METHODS

Ethics

Ethics approval was obtained from the University of British Columbia research ethics board.

Patients

Patients were considered eligible for participation if they had undergone implant-based breast reconstruction and if they had their final stage performed at least 1 year before initiation of the study.

Chart Review

A chart review was performed to compile data on the following demographic features: type of breast cancer, unilateral versus bilateral reconstruction, history of radiation or chemotherapy, complications, type of implant, follow-up time, age at second stage, timing of reconstruction, and comorbidities.

Design

A cross-sectional study design was employed. Patients were sent the BREAST-Q and the EORTC QLQC30 (Br23) questionnaires and a self-addressed, postage-paid return envelope by post. A $5 incentive gift card was included. Nonresponders were contacted by telephone 2 months after the first mailing. One additional copy of the questionnaires was distributed to nonresponders 3 months after the first mail-out. Additional patient data collected using the questionnaires included marital status, level of education, employment status, income, ethnicity, and medical history.

Questionnaires

The BREAST-Q was developed at the Memorial Sloan Kettering Cancer Center and the University of British Columbia.[32–34] This instrument measures health-related quality of life following breast surgery. The module used in this study was specific to breast reconstruction. This instrument encompasses six scales: (1) psychosocial well-being, (2) physical well-being, (3) sexual well-being, (4) satisfaction with breasts, (5) satisfaction with outcome, and (6) satisfaction with care. Field testing was performed at five centers in the United States and Canada (total $n = 1950$; test-retest $n = 491$; response rate, 72 percent). Item response theory (Rasch) analysis was used for item reduction and scale development. Cronbach's alpha for all 18 scales (three modules with six scales) ranged from 0.87 to 0.98 (0.88 to 0.96 for the breast reconstruction module). Test-retest reliability, as measured by intraclass correlation coefficients, ranged from 0.85 to 0.98.

The EORTC QLQC30 (Br23) was developed by the European Organization for Research and Treatment of Cancer at the Netherlands Cancer Institute.[35] This instrument evaluates health-related quality of life in cancer patients. The QLQC30 module incorporates nine scales (five functional, three symptom, and one global health-related quality of life). Validation was performed in 305 lung cancer patients from 13 countries. All scales, with the exception of role functioning, met the minimal standards for reliability (Cronbach's alpha coefficient >0.70). All interscale correlations were statistically significant. The reliability and validity of the questionnaire were consistent across the three language-cultural groups studied. Version 3.0 (used in this study) differs with regard to the response format of the physical function scale. It was tested for reliability in 623 head and neck cancer patients and was found to have better reliability (Cronbach's alpha = 0.8).[39]

The breast module encompasses questions that assess disease symptoms, side effects of treatment, body image, sexual functioning, and future perspectives. This module was tested in 496 patients.[40] Item convergent validity was confirmed. Cronbach's alpha coefficients met the 0.7 criterion for all scales in the American population sample. Selective scales distinguished clearly between patients differing in disease stage, previous surgery, performance status, and treatment modality.

The use of two questionnaires will allow the assessment of health-related quality of life after treatment for breast cancer [EORTC QLQC30 (Br23)] and measurement of postsurgical satisfaction (BREAST-Q). These questionnaires were chosen in favor of a generic measure, such as the Short Form-36,[29] as it was felt that a generic instrument would not be sensitive enough to detect differences between types of breast reconstruction patients.

Scoring

Scoring of the BREAST-Q was performed using QScore, which was developed according to the Rasch model.[41,42] All scales are scored on a 0- to 100-point scale. For all scales, higher scores indicate greater satisfaction/function.

Scoring of the EORTC QLQC30 (Br23) was performed using the SAS commands for scoring included in the EORTC QLQC30 Scoring Manual using SAS version 9.1.[43] All scales are scored on a 0- to 100-point scale. High scores on the global health status, physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning scales indicate good function. High scores on the symptom scales and financial difficulties scale indicate low function.

Sample Size Calculation

For the purposes of calculating a sample size, a difference in mean scores of 10 on a 100-point scale was assumed to be significant. This was determined by assuming an SD of 20, with one-half of an SD being the threshold of discrimination for change in health-related quality of life.[44] A total number of 126 alloplastic breast reconstruction patients, 63 in each arm, was determined to be the necessary sample size to detect a difference in mean change in score of 10 points between groups. This was calculated with a power of 80 percent using a two-sided p equal to 0.05 level test.

Statistical Analysis

Baseline characteristics were compared between saline and silicone recipients. Continuous variables were analyzed for normality. Normal data were compared using the t test. Categorical variables were assessed using Pearson's chi-square test. The mean scores on the BREAST-Q and EORTC QLQC30 (Br23) scales were compared using the t test. A multivariable linear regression model was employed to control for differences between the two groups and factors felt a priori to affect health-related quality of life following breast reconstruction. Adjusted scores for scales that showed a significant difference between the two groups were computed using the least square means method. A

0.05 criterion of statistical significance was employed for all tests. Statistical analysis was performed using SAS Statistical Software version 9.1.

Surgery

Alloplastic reconstruction was performed on an immediate or delayed basis, depending on patient presentation. All operations were performed by one of two surgeons. If radiotherapy was required for a patient undergoing immediate reconstruction, in all cases it was initiated after the completion of tissue expansion. Tissue expanders remained in situ for 3 months if there was no radiotherapy and for 6 months after radiotherapy. All saline implants were smooth round. Saline implant types included Allergan Style 68 or Mentor

Table 1. Patient Demographics

Variable	Saline (n = 68)	Silicone (n = 75)	Statistical Test	p
Age at survey completion				
Mean (SD)	55.62 (9.14)	52.27 (9.54)	t test	0.0341*
≤45 years	14.49	25.33	Chi-square	0.0687
>45 years	85.51	74.67		
Follow-up time, months				
Mean (SD)	53.58 (34.43)	31.36 (19.00)	t test	<0.0001*
Timing				
Immediate	61.76	82.67	Chi-square	0.0123*
			Fisher's exact	0.0070*
Delayed	35.29	17.33		
Both	2.94	0.00		
Unilateral versus bilateral, %				
Unilateral	44.12	40.00	Chi-square	0.6183
Bilateral	55.88	60.00		
Comorbidity				
None	66.18	65.33	Chi-square	0.9651
1	25.00	26.67		
≥2	8.82	8.00		
Complication				
None	50.94	44.78	Chi-square	0.7414
			Fisher's exact	0.7641
Minor (scarring, cellulitis, hematoma, wound healing delay, seroma)	15.09	22.39		
Major (exposure, failure)	1.89	2.99		
Capsular contracture	32.08	29.85		
Radiation, %				
No previous radiation	61.76	62.67	Chi-square	0.9115
Previous radiation	38.24	37.33		
Chemotherapy, %				
No previous chemotherapy	52.94	60.00	Chi-square	0.3950
Previous chemotherapy	47.06	40.00		
Stage of breast cancer, %				
Ductal carcinoma in situ	35.82	42.67	Chi-square	0.6536
Invasive	59.70	52.00		
Prophylactic	4.48	5.33		
Marital status				
Married	71.21	75.00	Chi-square	0.6158
Divorced/separated/single/widowed	28.79	25.00		
Level of education				
Some high school or diploma	16.67	11.11	Chi-square	0.2560
Some college or degree	65.15	77.78		
Some masters or degree	18.18	11.11		
Income				
<$20,000/year	5.36	7.69	Chi-square	0.7908
$20,000-$100,000/year	62.50	64.62		
>100,000/year	32.14	27.69		
Employment				
Homemaker	12.50	14.49	Chi-square	0.4268
Retired	20.31	11.59		
Full-time	50.00	60.87		
Part-time	17.19	13.04		
Ethnicity				
Caucasian	20.64	34.78	Chi-square	0.1307
Asian	74.60	57.97		
First nations	4.76	7.25		

*Denotes statistical significance.

Style 1600. Silicone implants included Allergan Style 10, Style 15, and textured Style 410 devices.

RESULTS

Response Rate

A total of 280 patients were identified. Sixteen patients were deceased and 17 patients had noncurrent addresses (neither responders nor nonresponders). Seventy-five silicone implant recipients and 68 saline implant recipients responded, for an overall response rate of 58 percent (143 of 247). Chart review was possible for 100 of the 104 nonresponders.

Patient Demographics

Saline and silicone implant recipients were compared for demographic variables, as shown in Table 1. Saline implant recipients were older than silicone recipients by approximately 3.5 years ($p = 0.034$). When the two groups were compared for older than or younger than 45 years, there was no statistically significant difference. The mean follow-up time was significantly higher for saline patients ($p < 0.0001$). The silicone implant group had a higher proportion of immediate reconstruction patients (83 versus 62 percent, $p = 0.012$).

Responders versus Nonresponders

Saline

Forty-eight saline nonresponders were compared with the 68 saline responders for the following variables: age at survey completion, mean follow-up time, timing of surgery, unilateral versus bilateral reconstruction, presence of comorbidity, complications, radiation exposure, chemotherapy, and stage of cancer (Table 2). Nonresponders had a significantly higher percentage of unilateral reconstructions compared with the responders (71 versus 44 percent, $p = 0.004$).

Silicone

The silicone implant recipient nonresponders ($n = 52$) and responders ($n = 75$) were compared for the same variables (Table 3). Nonresponders

Table 2. Responders versus Non-responders: Saline Patients

Variable	Responders ($n = 68$)	Nonresponders ($n = 48$)	Statistical Test	p
		Saline		
Age at survey completion				
Mean (SD)	55.6 (9.1)	57.2 (10.7)	*t* test	0.3920
≤45 years	14.5	18.8	Chi-square	0.4191
>45 years	85.5	81.3		
Follow-up time, months				
Mean (SD)	53.6 (34.4)	56.5 (26.7)	*t* test	0.6246
Timing				
Immediate	61.8	68.8	Chi-square	0.4146
			Fisher's exact	0.5594
Delayed	35.3	31.3		
Both	2.9	0		
Unilateral versus bilateral, %				
Unilateral	44.1	70.8	Chi-square	0.0044*
Bilateral	55.9	29.2		
Comorbidity				
None	66.2	48.7	Chi-square	0.2035
1	25.0	43.2		
≥2	8.8	8.1		
Complication				
None	50.9	65.9	Chi-square	0.1353
			Fisher's exact	0.1377
Minor (scarring, cellulitis, hematoma, wound healing delay, seroma)	15.1	6.4		
Major (exposure, failure)	1.9	6.4		
Capsular contracture	32.1	21.3		
Radiation, %				
No previous radiation	61.7	65.9	Chi-square	0.6462
Previous radiation	38.2	34.0		
Chemotherapy, %				
No previous chemotherapy	52.9	58.3	Chi-square	0.5652
Previous chemotherapy	47.1	41.7		
Stage of breast cancer, %				
Ductal carcinoma in situ	35.8	32.6	Chi-square	0.3015
Invasive	59.7	67.3		
Prophylactic	4.5	0.0		

*Denotes statistical significance.

Table 3. Responders versus Nonresponders: Silicone Patients

Variable	Responders (n = 75)	Nonresponders (n = 52)	Statistical Test	p
	Silicone			
Age at survey completion				
Mean (SD)	52.3 (9.5)	47.6 (6.7)	t test	0.0026*
≤45 years	25.3	44.2	Chi-square	0.0260*
>45 years	74.7	55.8		
Follow-up time, months				
Mean (SD)	31.4 (19.0)	35.5 (20.1)	t test	0.2451
Timing				
Immediate	82.7	84.6	Chi-square	0.4172
			Fisher's exact	0.4507
Delayed	17.3	14.5		
Both	0.0	1.9		
Unilateral versus bilateral, %				
Unilateral	40.0	58.0	Chi-square	0.0483*
Bilateral	60.0	42.0		
Comorbidity				
None	65.3	82.2	Chi-square	0.1181
1	26.7	15.6		
≥2	8.0	2.2		
Complication				
None	44.8	65.2	Chi-square	0.0242*
			Fisher's exact	0.0155*
Minor (scarring, cellulitis, hematoma, wound healing delay, seroma)	22.4	4.4		
Major (exposure, failure)	2.9	0.0		
Capsular contracture	29.9	30.4		
Radiation, %				
No previous radiation	62.7	63.5	Chi-square	0.9273
Previous radiation	37.3	36.5		
Chemotherapy, %				
No previous chemotherapy	60.0	48.1	Chi-square	0.1840
Previous chemotherapy	40.0	51.9		
Stage of breast cancer, %				
Ductal carcinoma in situ	42.7	41.7	Chi-square	0.2488
Invasive	52.0	58.3		
Prophylactic	5.3	0.0		

*Denotes statistical significance.

were younger by approximately 5.5 years (p = 0.002). Nonresponders had a higher proportion of unilateral reconstructions (58 versus 40 percent p = 0.048) and a significantly lower percentage of complications (p = 0.024).

BREAST-Q Scores

Mean scores were compared for saline versus silicone recipients. Silicone implant recipients scored higher on all nine subscales. This difference reached statistical significance for four of nine subscales: satisfaction with breast, psychological well-being, satisfaction with surgeon and sexual well-being (Table 4).

Linear regression was employed to adjust for factors determined to differ between the groups (age at survey completion, mean follow-up time, timing of surgery) and factors felt by the authors a priori to affect satisfaction with outcome (unilateral versus bilateral and radiotherapy). Multivariable linear regression analysis again showed a statistically significant association between silicone implant recipients and higher scores on the same four BREAST-Q subscales.

EORTC QLQC30 Scores

Saline and silicone implant recipients differed only for physical function with silicone patients having higher overall function (p = 0.019; Table 5). Saline implant recipients reported higher systemic therapy side effects on the Breast Module (p = 0.021; Table 6).

DISCUSSION

There has been extensive study of the psychological impact of mastectomy on a woman's body image.[45–52] These studies describe alterations in mood, sexuality, a feeling of disfigurement, and inhibition of social and occupational functioning. Roberts et al. report a diagnosis of depression or anxiety in 51 percent of patients in one study population.[48] Similar findings were reported by Maguire, including depressive reactions in 83 per-

Table 4. Group Comparisons BREAST-Q

Scale (range 0-100)	No. Completing	Mean Score	SD	Mean Score Difference†	*p*
Satisfaction with breast					
Silicone	75	63.8	15.2	6.8	0.0083*
Saline	67	56.9	15.1		
Satisfaction with outcome					
Silicone	75	75.4	17.6	5.9	0.0815
Saline	68	69.5	22.6		
Psychological well being					
Silicone	75	77.6	18.6	6.8	0.0322*
Saline	67	70.8	18.8		
Sexual well being					
Silicone	71	54.4	19.8	6.7	0.0562*
Saline	65	47.6	20.9		
Physical well being					
Silicone	74	76.2	14.9	2.8	0.2848
Saline	68	73.4	16.3		
Satisfaction with information					
Silicone	75	71.9	18.8	5.2	0.0879
Saline	68	66.7	17.1		
Satisfaction with surgeon					
Silicone	73	92.8	12.1	5.9	0.0193*
Saline	68	86.8	17.5		
Satisfaction with medical staff					
Silicone	72	90.9	16.4	4.9	0.1370
Saline	68	85.9	22.2		
Satisfaction with office staff					
Silicone	74	93.3	14.8	0.9	0.7127
Saline	67	92.3	16.9		

†Unadjusted scores.
*Denotes statistical significance.

cent of women and a lessening of sexual desire in 25 percent of studied patients.[52]

Research on psychological outcomes after breast reconstruction has primarily focused on (1) outcomes for lumpectomy and mastectomy patients with or without reconstruction, (2) outcomes for women receiving immediate versus delayed reconstruction, and (3) outcomes for women undergoing different types of reconstruction.[53] Several reports have shown that women who undergo breast reconstruction following mastectomy have less psychological distress and improved health-related quality of life compared with those who do not undergo reconstruction.[14,54–56] More recent reports have shown variable results when comparing outcomes in those who have undergone reconstruction.[18,21,28]

There are few studies comparing patient-reported outcomes for patients undergoing different types of breast reconstruction. Previous reports have compared autologous methods or autologous to alloplastic reconstruction.[57–60] These studies have been limited by the use of generic outcomes instruments and surgeon-generated assessment scales. Many surgeons feel that silicone gel implants provide a more natural result compared with saline in alloplastic reconstruction patients. Currently there are no published data to support this perception.

The current study attempted to answer a question that affects thousands of women undergoing alloplastic breast reconstruction each year: is there a difference in outcome when using a saline versus a silicone implant? In this patient population, responses to the BREAST-Q indicated a statistically significant higher overall satisfaction with breast reconstruction, higher psychological well-being, higher sexual well-being, and higher satisfaction with surgeon for silicone implant recipients. This finding was maintained after adjusting for variables that differed between groups. In addition, radiation exposure and unilateral versus bilateral reconstruction were included in the regression analysis, as these variables were felt a priori to influence overall satisfaction with outcome.

The adjusted mean score difference between groups ranged from 6.18 to 9.13 on the four subscales that showed a significant difference after linear regression using the least squares method. To determine the clinical significance of these differences, it is important to take into account the minimal important difference between two groups for scores on a health-related quality of life instrument. Norman et al. conducted a systematic review of the literature to identify studies that computed a minimal important difference from a number of quality of life instruments.[44] Their con-

Table 5. Group Comparisons: EORTC QLQC30

Scale (range 0-100)	No. Completing	Mean Score	SD	*p*
Global health status/QoL				
Silicone	72	79.9	18.1	0.1344
Saline	67	74.9	20.9	
Physical functioning				
Silicone	75	95.3	9.9	0.0193*
Saline	68	90.0	16.3	
Role functioning				
Silicone	75	92.7	19.2	0.1086
Saline	68	87.0	22.7	
Emotional functioning				
Silicone	73	77.9	20.6	0.6712
Saline	68	76.6	18.8	
Cognitive functioning				
Silicone	73	82.4	18.4	0.5832
Saline	68	80.6	20.1	
Social functioning				
Silicone	73	87.4	22.4	0.9381
Saline	68	87.7	23.9	
Fatigue				
Silicone	75	19.4	20.5	0.8680
Saline	68	18.9	17.6	
Nausea and vomiting				
Silicone	75	4.4	12.4	0.8890
Saline	68	4.2	11.3	
Pain				
Silicone	75	15.1	20.2	0.4374
Saline	68	17.9	22.6	
Dyspnea				
Silicone	75	5.8	13.8	0.1365
Saline	68	10.3	21.7	
Insomnia				
Silicone	75	26.2	28.6	0.4714
Saline	67	29.9	31.3	
Appetite loss				
Silicone	75	5.8	16.8	0.2502
Saline	68	9.3	19.8	
Constipation				
Silicone	75	9.33	20.9	0.3944
Saline	68	12.3	19.9	
Diarrhea				
Silicone	72	6.5	18.3	0.2987
Saline	67	9.9	20.9	
Financial difficulties				
Silicone	73	11.9	25.7	0.6667
Saline	68	13.7	25.3	

QoL, quality of life.
*Denotes statistical significance.

clusion was that the threshold of discrimination for difference in health-related quality of life scores (minimal important difference) was one-half of a standard deviation. In this study, the BREAST-Q subscales that showed significantly higher scores for silicone implant recipients had an adjusted mean score difference that closely approached one half of a standard deviation.

Results using the EORTC QLQC30 showed no statistically significant difference on any subscale, with the exception of higher overall physical function in silicone patients and higher systemic therapy side effects in saline patients. This is a cancer-specific questionnaire that examines function and symptom severity in cancer patients. In general, *condition-specific* measures allow greater responsiveness to intervention-related change compared with *generic outcomes measures*. Generic instruments are broad based and measure health-related quality of life in heterogeneous patient populations. Although generic measures may be reliable, they may not be sensitive enough to measure changes as a result of a surgical intervention.[61] Although the EORTC QLQC30 is not classified as a generic instrument, it is cancer-specific as opposed to surgery-specific. The questions included in the subscales do not specifically aim at determining function after *breast reconstruction*. Therefore, one would not expect patients to differ for these variables as they all share a diagnosis of cancer. The

Table 6. Group Comparisons: European Organization for the Research and Treatment of Cancer Breast Module

Scale (range 0-100)	No. Completing	Mean Score	SD	*p*
Body image				
Silicone	74	75.2	21.6	0.2206
Saline	67	70.6	22.5	
Sexual functioning				
Silicone	73	29.2	25.3	0.6387
Saline	65	31.3	26.1	
Sexual enjoyment				
Silicone	49	54.4	27.8	0.5806
Saline	44	57.7	29.7	
Future perspectives				
Silicone	74	66.2	29.5	0.3434
Saline	66	61.6	27.6	
Systemic therapy side effects				
Silicone	74	13.3	11.6	0.0211*
Saline	67	18.6	15.7	
Breast symptoms				
Silicone	75	7.2	11.9	0.1486
Saline	66	11.1	19.4	
Arm symptoms				
Silicone	75	11.3	15.2	0.2764
Saline	66	14.5	19.7	

*Denotes statistical significance.

EORTC QLQC30 Breast Module more specifically examines function after treatment for breast cancer but does not focus on quality of life after a *surgical intervention*. This questionnaire is nonspecific to breast reconstruction patients and is likely not sensitive enough to identify differences between patients undergoing different types of breast reconstruction.

A limitation of a survey design study is response rate, which may predispose to selection bias. Analysis of nonresponders showed a higher proportion of unilateral breast reconstructions in saline and silicone nonresponders. It is possible that unilateral breast reconstruction patients are more satisfied overall. This was not strongly supported on regression analysis, which showed that unilateral versus bilateral reconstruction was not a significant predictor of patient score. In addition, this should not affect the difference in scores between groups because both groups had a higher proportion of bilateral responders.

There was a decreased rate of complications and younger age in silicone nonresponders. The fact that nonresponders had a lower rate of complications would not artificially inflate scores for the silicone responders; in fact, the reverse is likely true. It is unknown whether younger patients are more satisfied with breast reconstruction than older patients. The 5.5-year age difference between silicone responders and nonresponders may have artificially decreased scores for the responders if advanced age correlates with lower satisfaction. The linear regression model attempts to control for these potential limitations as age was a significant predictor for patient scores on the satisfaction with breast subscale and on the satisfaction with overall outcome subscale on the BREAST-Q.

A further limitation of the study is the inability to control for systematic differences in patient characteristics such as risk adversity and/or personality traits. If patients who choose silicone implants are systematically different from patients who choose saline implants, this may influence scores. By adjusting for a large number of measurable variables we have attempted to control for such differences.

Finally, the use of a multidimensional instrument with multiple scales is another limitation of this study. All *p* values must be interpreted with this in mind. The Bonferroni correction for multiple testing was not employed, as this method is based on the assumption that all tests are independent. Because the individual scales of a multidimensional instrument are inter-independent, correction in this setting may overinflate *p* values.

CONCLUSIONS

This is the first study to address differences in satisfaction between silicone and saline implant recipients following breast reconstruction. Responses on a surgery-specific instrument show silicone recipients to have overall higher satisfaction with the reconstructed breast(s). After adjusting for age, follow-up time, radiation therapy, and unilateral versus bilateral surgery, silicone recipi-

ents scored an average of 64 points for overall satisfaction with breast while saline patients scored 57 points. Similar results were seen for sexual well-being, psychological well-being, and overall satisfaction with surgeon. Findings using the EORTC-QLQC30 revealed no statistically significant difference in overall global health status. Thus, it may be concluded that increased satisfaction in silicone implant recipients found using the BREAST-Q is not equivalent to increased overall global health as measured by the EORTC-QLQC30. The findings of this study provide reliable data that will allow surgeons to adequately inform their patients preoperatively regarding the expected outcomes of breast reconstruction using silicone and saline implants.

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