

# Patient Satisfaction and Surgical Outcome After Oncoplastic Reconstruction following Radical Lumpectomy *Versus* Standard Lumpectomy: A Retrospective Cohort Study

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## **ABSTRACT**

**Objective:** Oncoplastic reconstruction (OR) enables widening of the indications for breast conserving therapy (BCT) and is redefining the limits of breast conservation. We examined the outcome and satisfaction of patients undergoing OR after radical lumpectomy (excision of more than 25% of the breast volume) and compared it to the outcome of women undergoing OR after standard lumpectomy.

**Materials and Methods:** A retrospective, cohort study, including all patients undergoing OR after BCT between 2009 and 2018, was conducted. The ratio of volume of excision to breast volume was calculated using imaging studies. The study group included women that had more than 25% of their breast volume removed. The remainder formed the control group. Demographic characteristics, oncological treatment, and operation properties were collected. We compared post-operative complications, margin status and need for further surgery, as well as patient satisfaction, evaluated using the BREAST-Q Questionnaire.

**Results:** One hundred and fifty women were included, of whom 24 (16%) comprised the study group with a mean breast volume reduction of 39%, while the remainder (mean volume reduction 8%) served as controls. Patient, tumor characteristics and treatment were comparable. There was a non-significant higher proportion of women in the radical group that underwent a second operation due to complications or positive margins [4/24 (16.7%) vs. 14/126 (11%), p = 0.4). Physical well-being was similar but satisfaction with breasts and with outcome was slightly lower for the study group. These differences did not reach statistical significance.

**Conclusion:** Surgical outcome and patient satisfaction in women undergoing very extensive breast resections with OR are comparable to standard resections.

Keywords: Oncoplastic reconstruction; radical lumpectomy; BREAST-Q; breast conserving therapy; patient satisfaction

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# **Key Points**

- The ability to reconstruct the breast using oncoplastic techniques, allows for extension of the indications for breast conservation.
- Outcome of radical lumpectomies (removal of more than 25% of breast volume) was compared to outcome of standard lumpectomies with oncoplastic reconstruction.
- Surgical outcome and patient satisfaction were comparable in women undergoing radical vs. standard lumpectomy.

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# Introduction

Multiple prospective randomized trials reported similar disease-free and overall survival for breast conserving therapy (BCT) and mastectomy. As a result, BCT became the standard of care for patients with early breast cancer (1, 2). Nevertheless, some contraindications for BCT remain. These include multifocal breast cancer (at least two tumor foci in the same quadrant), multicentric breast cancer (at least two foci in different breast quadrants) (3) and large tumor to breast size ratio. The concern in these cases is a higher risk of recurrence and inferior cosmetic results (4). With the introduction of immediate reconstruction and collaboration between Breast and Plastic surgeons (oncoplastic surgery), cosmetic results following BCT have improved (5, 6), especially in large resections. The advantages of oncoplastic surgery include wider surgical margins (7) more efficient post-operative radiation treatment, especially in large and fatty breasts (8, 9), and improved oncologic and aesthetic outcomes (10-12).

As oncoplastic surgery minimizes breast deformation following wide excisions, it allows surgeons to "push the limits" and apply BCT in very extensive tumors and has re-defined the limits of breast conservation. Clough classified oncoplastic procedures according to the volume of excision (13). He defined removal of up to 20% of the volume as level I excision and removal of 20%-50% as level II excision. Level II excisions require more advanced oncoplastic techniques. Silverstein coined the term "extreme oncoplasty" for cases defined as "a patient who in most physicians' opinions requires a mastectomy" but underwent BCT with oncoplastic reconstruction (OR) (14). Several studies (14-16) reported outcomes of OR in selected patients with multifocal/multicentric tumors or a tumor that spanned more than 5 cm. The definition of Extreme Oncoplastic surgery used in all these reports does not take into consideration the breast size of the patient and may include cases that are within the standard indications for BCT with OR. The main factor that effects cosmetic outcome and need for OR is the proportion of volume excised (17, 18). Based on Clough's classification, we chose the proportion of volume removed to define the group of women undergoing extensive excisions. However, we chose the cutoff of 25% to define the term radical lumpectomy to include only the most extensive excisions that definitely required advanced oncoplastic techniques. The purpose of the current study was to examine the outcome of women undergoing radical lumpectomies with immediate OR, and to assess if it is comparable to the outcome of patients undergoing OR following standard lumpectomies.

# Materials and Methods

This retrospective, cohort study was approved by the Institutional Review Board and Ethics Committee of Tel Aviv University (TLV-17-0453). All consecutive breast cancer patients undergoing BCT with OR by a team of general and plastic surgeons, between the years 2009 and 2018 in our medical center, were included in the study.

The patients were divided into two groups based on the extent of tissue resection. The study group included patients that had a "radical lumpectomy" whereas the control group included patients that had a standard lumpectomy excision.

Radical lumpectomy was defined as an excision of more than 25% of the breast volume. This was determined by dividing the calculated volume of resection by the calculated breast volume. The volume of resection was calculated from the imaging at the time of diagnosis or

at the time of needle localization prior to surgery using the formula for calculation of a sphere volume:

$$v=rac{4}{3}\pi r^3$$
 ; where r is half of the largest diameter of the tumor as visualized on imaging.

The volume of the breast was calculated using Kalbhen's formula (19):

$$v = \frac{\pi}{4} * h * w * c$$

Where w is the lateral-to medial longest dimension on cranio-caudal (CC) view, h is the anterior to posterior longest dimension (both w and h are estimated from the mammographic images), and c is the compression thickness of the breast as routinely reported by the mammography technician in the mammography report. As the compression thickness varies with the degree of compression, we used all measurements of the volume calculation from one exam. Most mammography system (Bedford, MA, USA).

When the ratio of the excision volume divided by the breast volume was larger than 0.25, the case was defined as a radical lumpectomy and allocated to the study group.

For both groups, the data collected included demographic and tumor characteristics, treatment details, operations properties, complications and histopathological findings. Intraoperative assessment of the margins was not routinely done due to the extensive analyses needed to rule out margin involvement. Follow-up time was defined as time elapsed between the dates of the surgery and the phone questionnaire. Patient satisfaction was evaluated using the BREAST-Q questionnaire (20). This questionnaire was developed to create a patient-reported outcome measure that would provide essential information about the impact and effectiveness of breast surgery. The BREAST-Q has a modular, procedure-specific structure with scales that evaluate both satisfaction and quality of life. Psychometric evaluation reveals high reliability, validity and responsiveness to surgical intervention across all scales (21). The reconstruction module is comprised of nine parts; each part includes a scale of up to 5 answers. In this study, parts 1, 3, 4 and 6 in the reconstruction module questionnaire were used.

All consecutive patients were contacted by phone, and asked to consent to be interviewed by investigators other than the treating surgeons. The questionnaire was filled out over the phone. Women were excluded from this part of the study if they had language limitations, or if they ultimately underwent a completion mastectomy because of positive margins.

The characteristics of the two groups were compared using the student's t-test for continuous variables and chi-square or Fisher's exact test for parametric variables. For analysis purpose the module's results were transformed to a normal scale of 100 points as recommended by the creators of the questionnaire.

Linear regression models were created in order to examine the association between extent of resection and patient satisfaction while controlling for possible confounders. Four models were created for the four outcomes that were assessed by the questionnaire. All tests were two-sided and a *p*<0.05 was considered significant. Statistical analysis

was completed using IBM SPSS Statistics for Windows, version 23 (IBM Corp., Armonk, N.Y., USA).

## Results

One hundred and sixty-eight patients underwent BCT with immediate OR during the study period. After excluding patients with benign disease, patients who passed away, and two women for whom extent of excision could not be determined, 150 women remained in the study. Patient and tumor characteristics are summarized in Table 1.

Table 1. Cohort characteristics

	Standard (n = 126)	Radical (n = 24)	<i>p</i> -value
Mean follow up, years (SD)	2.1 (1.8)	1.2 (2.3)	0.04
Mean age, years (SD)	52.6 (12)	52.9 (9)	0.9
Mean BMI (SD)	26.8 (5.1)	26.8 (6.5)	0.9
Smoking history, n (%)			
No	59 (66)	13 (68)	
Current	18 (20)	3 (16)	
Past	13 (14)	3 (16)	0.9
Grade, n (%)			
1	9 (7)	0	
2	44 (36)	12 (50)	
3	55 (45)	10 (42)	0. 5
Lobular, other, unknown	14 (11)	2 (8)	0. 5
Receptor status, n (%)			
Luminal	91 (74)	19 (79)	
Triple negative	8 (7)	2 (8)	0.7
HER-2 positive	24 (20)	3 (13)	0.7
T stage (at diagnosis), n (%)			
In situ	11 (9)	5 (22)	
1	48 (39)	7 (30)	
2	44 (36)	9 (39)	
3+	19 (17)	2 (11)	0.4
Unknown	4 (3)	1(4)	0
Node positive at diagnosis	53 (43)	8 (33)	0.4
Neoadjuvant treatment, n (%	s)		
None	71 (58)	13 (54)	
Chemotherapy	24 (20)	7 (29)	
Hormonal	10 (8)	1 (4)	0.7
Chemotherapy and HER-2neu targeted therapy	17 (14)	3 (13)	
Localization type, n (%)			
None	12 (10)	0	
Ultrasound	48 (38)	7 (29)	
Mammography	49 (39)	14 (58)	
MRI	8 (6)	1 (4)	0.3
Combination	8 (6)	2 (8)	

Twenty-four (16.7%) cases were included in the radical lumpectomy group; the mean ratio of excision volume to breast volume was 0.39. The control group consisted of 126 (84%) women with a mean volume ratio of 0.08.

The mammographic preoperative localization of one of the radical lumpectomy patients is depicted in Figure 1. Preoperative and post-radiation images are depicted in Figure 2.

Table 1. continued

	Standard (n = 126)	Radical (n = 24)	<i>p</i> -value
Mean number of localizing needles (SE)*	2 (0.1)	3.6 (0.2)	<0.001
Type of reconstruction, n (%)			
Reduction	81 (64)	13 (54)	
Reduction with mastopexy	4 (3)	0	
Mastopexy	37 (29)	11 (46)	
Augmentation	2 (2)	0	0.7
Other	2 (2)	0	
Median specimen weight, grams (SE)*	94 (10)	177 (26)	0.005**
Margin status, n (%)			
Involved or close	15 (12)	6 (25)	0.2
Re-operation, n (%)			
Positive margin	10 (8)	2 (8)	
Complication (debridement, closure of dehiscence)	4 (3)	2 (8)	0.4
Complications (total), n (%)	11 (9)	3 (13)	
Infection	7 (6)	1 (4)	
Dehiscence; necrosis requiring surgery	4 (3)	2 (8)	0.5
Adjuvant treatment, n (%)			
Chemotherapy	20 (16)	4 (17)	0.9
Chemotherapy and HER-2neu targeted therapy	4 (3)	0	
Hormonal	99 (81)	17 (71)	0.3
Adjuvant radiation, n (%)	112 (92)***	24 (100)	0.4
Recurrence, n (%)			
Loco-regional	7 (6)	2(8)	
Distant	3 (3)	0	0.2
Mortality	6(5)	1(4)	0.8

<sup>\*</sup>Lumpectomy specimen only, reduction not included.

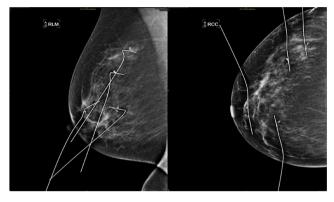
<sup>\*\*</sup>Mann-Whitney U test.

<sup>\*\*\*</sup>Recommendation for radiation after lumpectomy was based on women's' characteristics (age and comorbidities) and final pathology.

BMI: Body Mass Index; HER-2: human epidermal growth factor receptor 2; MRI: magnetic resonance imaging; SE: standard error; SD: standard deviation; n: number

The two groups were comparable in respect to demographic and tumor characteristics, as well as neoadjuvant and adjuvant treatment (Table 1). The T stage was similar in both groups. However, diagnosis of ductal carcinoma *in situ* (DCIS) was more prevalent in the study group (n = 5, 22%) compared to the control group (n = 11) (9).

The mean follow-up time was slightly longer for the control group ( $2.1\pm1.8$  years vs.  $1.2\pm2.3$  in the study group). The mean number of needles inserted to mark the tumor for excision was higher in the study group, ( $3.6\pm0.2$  compared to  $2\pm0.1$  in the



**Figure 1.** Mammographic preoperative localization of breast tumor prior to radical lumpectomy. The patient completed neoadjuvant treatment for extensive luminal infiltrating ductal carcinoma with nodal involvement. She underwent radical lumpectomy, sentinel node biopsy and oncoplastic reconstruction. Pathology showed residual DCIS and atypical ductal hyperplasia with clear margins, and negative sentinel lymph nodes

DCIS: ductal carcinoma in situ

control group). The median specimen weight was higher in the study group (177±26 grams vs. 94±10 in the control group). In both groups, most women underwent OR using breast reduction techniques (n = 13; 54% of the study group; and n = 81; 64% in the control group). Most women (n = 143, 95%) had a bilateral procedure. In 17 (11%) patients, this was done for a bilateral cancer or a high-risk lesion in the contralateral breast, and in the remainder of cases, the contralateral procedure was done in order to achieve symmetry. Close or positive pathology margins were found in 6 (25%) women in the study group compared to 15 (12%) in the control group); this difference was not statistically significant. Two patients (8%) in the radical lumpectomy group underwent relumpectomy because of involved margins, whereas in the standard lumpectomy group, 10 patients (8%) had an additional operation. Seven required a re-lumpectomy, three required a mastectomy and one patient required a sentinel lymph node biopsy. Two women with involved margins were planned to undergo a repeat surgery (mastectomy) after completing adjuvant chemotherapy, but subsequently refused.

Three patients (13%) in the radical lumpectomy group experienced complications: two (8%) required revision of the surgery within one month of the original surgery; one underwent debridement and closure of the wound and the other required revision because of nipple congestion. In the control group, 11 (9%) patients had a complication, four (3%) of them requiring revisional surgery; three underwent debridement, one of them of the nipple and one closure of wound dehiscence.

The BREAST-Q questionnaire was completed by 95 (63%) patients, 15 (63%) of whom were in the study group and the remainder in the control group (80; 64%), (Table 2).

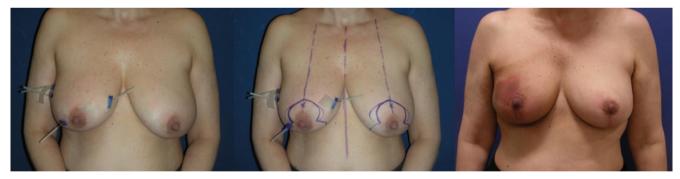


Figure 2. From left to right: Preoperative needle localization (a), markings (b) and cosmetic result one-month post-radiation (c) of a patient undergoing radical lumpectomy

Table 2. Patient satisfaction after breast conserving surgery with oncoplastic reconstruction as assessed by the BREAST-Q questionnaire (women who had a second surgery were included unless final surgery was a mastectomy)

	Standard lumpectomy (n = 80)	Radical (n = 15)	<i>p</i> -value
Mean time to survey, years (SE)	3.3 (0.3)	2.2 (0.5)	0.08
Mean Satisfaction with Breasts score (SE)	73 (2.1)	63 (6.1)	0.08
Mean Satisfaction with Outcome score (SE)	81 (2.5)	73 (6)	0.16
Mean Psycho Social Well-being score (SE)	82 (2.1)	78 (4.9)	0.45
Mean Physical Well-being: Chest score (SE)	72 (2.1)	74 (4.9)	0.76
SE: standard error; n: number			

Based on the BREAST-Q, satisfaction with breasts and with outcomes were slightly lower for the group undergoing radical lumpectomy. However, these differences did not reach statistical significance. On multivariate linear regression analysis (Table 3), no association was found between extent of surgery, patient characteristics and the different outcomes assessed by the modules of the BREAST-Q.

## **Discussion and Conclusion**

We report the results of women undergoing radical lumpectomy with immediate OR. The characteristics of the women and their tumors were similar to those of women undergoing standard lumpectomy with immediate OR. We found that margin status, complication rates and patient satisfaction were comparable to women undergoing standard lumpectomy with immediate OR. Since Silverstein first coined the term "extreme oncoplasty" in 2015 (14), suggesting the concept of OR in patients that "normally require a mastectomy", several other studies have confirmed the feasibility of extreme oncoplastics, and reported long-term outcomes (18, 22).

Koppiker et al.(16) reported results in 39 women undergoing extreme OR followed by radiation. There was no comparison group in this report. They found no major complications, and three minor complications (seroma and wound healing problems treated conservatively). The results of the questionnaire, collected 12 months after the operation, showed good satisfaction with breasts (78.0±16.6) and with outcome (85.7±13.7) and high psychosocial (90.8±11.5) and sexual wellbeing (75.8±11.7). Crown et al. (15) reported the results of 111 women undergoing extreme OR. In this study the complication rate was 16%, with 2% having revisional surgery. More than half needed a second surgery for positive margins, usually a re-excision. This high proportion maybe explained by the limited use of neoadjuvant treatment in this cohort (5%). Recurrence rates among women completing radiation were low (1.1%). Cosmetic outcome was evaluated by the operating surgeons, using the Harvard Breast Cosmesis Scale. Good to excellent cosmetic outcome was reported in 95% of the patients, with patients undergoing a second surgery and those experiencing complications having slightly lower rates. Acea Nebril et al. (23) assessed patient

Table 3. Multivariate analysis: satisfaction with breasts; satisfaction with outcome; psychosocial well-being; physical well-being

	В	Standard error	Standardized B	<i>p</i> -value
Satisfaction with breasts				
Age, years	-0.14	0.19	-0.10	0.49
Smoking	-5.85	5.57	-0.16	0.30
BMI	0.10	0.50	0.03	0.85
Radical lumpectomy	-5.32	6.02	-0.13	0.38
Specimen weight, grams	-0.03	0.03	-0.14	0.40
Time between surgery and questionnaire, days	-0.00	0.00	-0.13	0.39
Satisfaction with outcome				
Age, years	-0.42	0.20	-0.30	0.04
Smoking	-8.53	5.70	-0.21	0.14
BMI	-0.29	0.51	-0.09	0.57
Radical lumpectomy	-5.92	6.17	-0.14	0.34
Specimen weight, grams	-0.00	0.03	-0.01	0.94
Time between surgery and questionnaire, days	-0.00	0.00	-0.11	0.48
Psychosocial well-being				
Age, years	-0.026	0.20	-0.18	0.20
Smoking	-10.59	5.87	-0.26	0.08
BMI	-0.12	0.53	-0.04	0.82
Radical lumpectomy	2.09	6.35	0.05	0.74
Specimen weight, grams	-0.06	0.03	-0.29	0.08
Time between surgery and questionnaire, days	0.00	0.00	0.11	0.45
Physical well-being: chest				
Age, years	0.13	0.21	0.09	0.55
Smoking	-1.47	6.28	-0.04	0.82
BMI	-0.18	0.54	-0.05	0.73
Radical lumpectomy	4.63	6.71	0.11	0.49
Specimen weight, grams	-0.04	0.03	-0.13	0.28
Time between surgery and questionnaire, days	0.00	0.01	0.13	0.41
BMI: Body Mass Index				

satisfaction using the same questionnaire. They found that patients who underwent extreme oncoplastic breast conserving surgery had significantly greater satisfaction with their breasts (82.5% in the extreme oncoplastic group, 76.3% in the standard oncoplastic group), with higher outcome scores (88% vs. 82.1%) and higher psychological well-being scores (78.7% vs. 67.2%). These reports do not take into consideration the breast size of the patient. The volume of the remaining breast is crucial. For example, removal of a 5 cm tumor in a D-cup breast is smaller than the excision of breast tissue in an average breast reduction. The concept of multicentric disease can be misleading as well, as two tumors located in different quadrants, (for example at 2 and 4 o'clock) are considered as multicentric disease, vet the distance between the two may enable BCT without a negative impact on cosmetic outcome even without OR. We chose therefore, to use the ratio of volume of excision to calculated breast volume in order to define the extent of excision and coined the term "Radical lumpectomy" to describe OR for lumpectomies involving the excision of more than 25% of the breast volume. This definition is more radical than the "extreme Oncoplastic reconstruction" definition, which explains our relatively small study group. Importantly, we used standardized definitions for the assessment of the excision and breast volumes, making this definition reproducible.

This study has several limitations. It is a retrospective study of patients from a single institution. The number of patients in the study group is small, which may limit the power of the study to find small differences in the different outcomes. The women were approached at different follow-up times from the surgery with the study group having a significantly shorter median follow-up time compared to the control group. As cosmetic results change over time, the difference in followup time may have had an impact on patient satisfaction. Although volumes of excision and breast were calculated with standard formulae, the measurement of the different components of the formula is operator dependent. This may compromise the reproducibility of these calculations. The BREAST-Q questionnaire was completed over the phone by 63% of the women in the study, which may point to a selection bias. This might have impacted the answers, especially in more of the intimate questions regarding self-image; we tried to limit this concern by approaching the patients by investigators other than the treating surgeons. It is assumed that this limitation is nondifferential and affected the two groups similarly and thus should not impact the results of the study.

In conclusion, in this preliminary study, examining outcome of oncoplastic reconstruction after radical lumpectomies, which was defined as removal of more than 25% of the breast volume for the purpose of this study, surgical outcome and patient satisfaction were comparable in the study and control groups. Long term outcome and oncological safety need to be examined.

Ethics Committee Approval: This retrospective, cohort study was approved by the Tel Aviv Sourasky Ethics Committee (approval no: TLV-17-0453).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

# **Authorship Contributions**

Surgical and Medical Practices: E.B., Y.N., O.G., Y.B., E.A., T.S.M.; Concept: E.B., Y.B., E.A., T.S.M.; Design: Y.B., T.S.M.; Data Collection and/or Processing: E.B., Y.N., O.G., Y.B., T.S.M.; Analysis and/or Interpretation:

E.B., Y.N., O.G., ,Y.B., T.S.M.; Literature Search: E.B., T.S.M.; Writing: Y.N., O.G., Y.B., E.A., T.S.M.

Conflict of Interest: No conflict of interest was declared by the authors.

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