Immediate Tissue Expander/Implant Breast Reconstruction after Salvage Mastectomy for Cancer Recurrence following Lumpectomy/Irradiation

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Background: The objective of this study was to analyze early complications and long-term outcomes in patients undergoing salvage mastectomy and immediate tissue expander/implant reconstruction for cancer recurrence following breast conservation therapy (lumpectomy/irradiation).

Methods: A review of all tissue expander/implant reconstructions performed by a single surgeon over an 11-year period from 1997 to 2008 was performed. Two patient cohorts were identified: (1) patients who underwent salvage mastectomy for a cancer recurrence following prior breast conservation therapy, and (2) patients who underwent primary mastectomy without a history of prior irradiation. The incidence of early complications and long-term outcomes were determined for each cohort.

Results: Immediate, tissue expander/implant reconstruction was initiated in 1699 patients. One hundred twenty-one patients had a history of breast conservation therapy (lumpectomy/irradiation), and 1578 did not have a history of prior irradiation. The incidence of early complications was significantly higher in the irradiated cohort compared with that in the nonirradiated cohort (29.7 percent versus 15.5 percent; $p \le 0.001$). The most common complication in both groups was mastectomy flap necrosis (18.0 percent in the irradiated group and 7.7 percent in the nonirradiated group; p < 0.001). Six hundred ninety-seven patients had long-term follow-up data available. Most previously irradiated patients had good or very good results, whereas most nonirradiated patients had excellent results (p = 0.04; Mann-Whitney U test).

Conclusions: Carefully selected patients who have had prior breast conservation therapy who require salvage mastectomy can successfully complete postmastectomy tissue expander/implant reconstruction. The rate of early complications in this patient group is higher than in the nonirradiated cohort but remains acceptable. (*Plast. Reconstr. Surg.* 129: 341, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, II.



he relative simplicity, rapid recovery, and elimination of donor-site morbidity associated with tissue expander/implant breast reconstruction is appealing to many women. However, the efficacy of implant-based reconstruction in the setting of previously irradiated tissues remains controversial. Complication rates following tissue expander/implant breast reconstruction in patients undergoing salvage mastectomy and impatients undergoing salvage mastectomy and im-

mediate breast reconstruction have been reported to be as high as 70 percent in some series. Although these series are plagued with low patient numbers (range, three to 35), the reported high complication rates have suggested that patients with a history of prior irradiation be ineligible for implant-based reconstruction. Similar reports have also advocated autogenous tissue reconstruction.

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tion over implant-based reconstruction because of superior aesthetic outcomes and greater durability of results.

Recent advances in expander technology, the advent of the skin-sparing mastectomy, and alterations to radiation dosing regimens have enabled more patients with a history of irradiation to undergo tissue expansion with success than previously reported. For tissue expander/implant reconstruction to be accepted as an option in selected patients presenting for immediate reconstruction following salvage mastectomy, it must be demonstrated that the procedure has an acceptable rate of complications. It must similarly be shown that the long-term aesthetic outcomes are acceptable.

A single surgeon's extensive experience with immediate tissue expander/implant breast reconstruction in women undergoing salvage mastectomy for cancer recurrence following breast conservation therapy (lumpectomy/irradiation) provides an opportunity to evaluate these outcomes in a uniformly treated population. Such an assessment will assist patients and surgeons alike in making informed decisions regarding reconstructive options.

The main objective of this study was to review a single surgeon's 11-year experience with immediate tissue expander/implant breast reconstruction in a selected group of previously irradiated women. An analysis of early surgical complications was performed and compared with the complication rate of nonirradiated women undergoing immediate tissue expander/implant reconstruction during the same time period. Late complications (capsular contracture rate, revisionary procedures), long-term aesthetic results, and patient satisfaction were also evaluated.

PATIENTS AND METHODS

A review of all tissue expander/implant breast reconstructions performed by the senior author (P.G.C.) over the 11-year period from December of 1997 to December of 2008 was executed. During this period, 2089 two-stage expander/implant reconstructions were performed. Patients who underwent combined autogenous tissue-expander/ implant reconstructions received postoperative or perioperative radiation therapy, had a history of irradiation because of Hodgkin disease, or had delayed breast reconstruction were excluded. Two cohorts of patients undergoing immediate tissue expander/implant reconstruction were then identified (n = 1699): (1) patients who underwent salvage mastectomy for cancer recurrence following prior breast conservation therapy (n = 121), and (2) patients who underwent primary mastectomy without a history of prior irradiation (n = 1578).

A prospectively maintained breast reconstruction database was analyzed with respect to reconstructive, complication, and outcomes data on tissue expander/implant reconstructions in 1699 patients. Complications such as skin flap necrosis, infection, hematoma, seroma, delayed wound healing, failed expansion, and expander/implant loss were evaluated. Early complications were defined as those occurring less than 12 months from initiation of reconstruction. All patients who returned for routine follow-up at least 1 year after completion of breast mound reconstruction had long-term outcome data entered into the database. These long-term outcome data included overall aesthetic results, capsular contracture grade, revisionary procedures, and patient satisfaction. Overall aesthetic results were graded as excellent, very good, good, fair, or poor. Capsular contracture was evaluated using the modified Baker classification.² Revisionary procedures evaluated were as follows: tissue expander replacement, implant replacement or modification, and need for a latissimus dorsi flap. Patient satisfaction was graded according to the patient's response to the following questions: "Are you satisfied with your result overall?" and "Knowing what you know now, would you undergo the same procedure again?" Demographic data (i.e., age, height, weight, and self-reported preoperative bra cup size) and reconstruction data (i.e., laterality, time to exchange, expander, and implant type, implant volume, and adjuvant and/or neoadjuvant therapies received) were entered prospectively into the database.

Surgical Methods

Patients were selected as candidates for tissue expander/implant reconstruction based on a favorable assessment of skin and soft-tissue quality and scars. Surgical methods have been described previously.^{3,4} All reconstructions were performed using the Inamed Style 133FV textured, anatomical expander (Inamed, Santa Barbara, Calif.). Expanders were placed submuscularly. Closed-suction drains were placed routinely in the subcutaneous plane. Mastectomy flaps were tailored to minimize skin excess and to maximize future breast contour. After wound closure, intraoperative expansion was performed to tissue tolerance. Up to 50 percent of the tissue expander volume was generally placed, thus filling the subpectoral cavity and preventing skin contracture.

Perioperative antibiotics were routinely administered and continued until all drains were removed.

In the absence of skin flap necrosis or infection, postoperative expansions generally began 10 to 14 days after surgery. Expansions were performed until tissue tolerance or patient discomfort was experienced. The final expander volume was usually 20 percent greater than the recommended volume of the expander to create a looser skin envelope; thus, there was a greater potential for ptosis.

During the second stage, a full circumferential capsulotomy was performed. Along with the capsulotomy, the inferomedial border of the pectoralis muscle and the inframammary fold were released. The area of the inframammary fold was then advanced and approximated to the anterior chest wall with interrupted, permanent sutures. The operating table was routinely placed in an upright sitting position and symmetry was evaluated throughout the procedure. Various implant sizers were evaluated and the final prosthesis was selected.

Statistical Analysis

Descriptive statistics of all demographic, reconstructive, and outcome data were reported as a mean (range), or as the percentage of patients having the characteristic. Comparisons for categorical variables (i.e., occurrence of complications, laterality, final implant size, obesity, and receipt of adjuvant chemotherapy therapy) were given as Fisher's exact tests or chi-square tests where appropriate. Comparisons for ordinal data (i.e., aesthetic outcome and capsular contracture grade) between two groups were given as Mann-Whitney U tests. The significance level was set at the p=0.05 level. SPSS statistical software was used (SPSS, Inc., Chicago, Ill.).

RESULTS

Over the 11-year period from December of 1997 to December of 2008, tissue expander/implant breast reconstruction was initiated in 2089 patients. In total, 1699 were considered eligible for this current series. All cases were performed by the senior author (P.G.C.).

Early Complications Analysis

Evaluation of early complications was performed in 1699 patients: 121 patients who underwent salvage mastectomy for cancer recurrence following prior breast conservation therapy, and

1578 patients who underwent primary mastectomy without a history of prior irradiation. The overall incidence of early complications was significantly higher in the patients in the irradiated cohort (29.8 percent) compared with the patients in the nonirradiated cohort (15.5 percent) (p < 0.001; chi-square test). The most common early complication in both groups was mastectomy flap necrosis. The incidence of necrosis was significantly higher in the irradiated cohort (18.0 percent) than in the nonirradiated cohort (7.7 percent) (p< 0.001). There was no significant difference when comparing other types of complications individually, including infection, hematoma, delayed wound healing, failed reconstruction, and seroma. All early complications are outlined in Table 1.

Outcome Analysis

Long-term follow-up data on 695 patients with a minimum of 1-year follow-up after completion of tissue expander/implant reconstruction was entered into the prospectively maintained, reconstructive database. Mean total follow-up was 46.4 months (range, 12 to 127 months; n = 48) in the irradiated cohort and 43.3 months (range, 12 to 264 months; n = 647) in the nonirradiated cohort.

The two cohorts with available long-term follow-up data did not differ with respect to laterality, body mass index, or preoperative bra cup size. Although patient age was significantly different in the two cohorts, this difference was not clinically significant. There was no difference in the percentage of patients who completed reconstruction of the breast mound. The proportion of patients

Table 1. Early Complications in Patients with and without a History of Irradiation

Prior Radiotherapy (%)	No Radiation History (%)
121	1578
22 (18.2)	122(7.7)
10 (8.3)	75 (4.8)
1 (0.8)	28 (1.8)
, ,	, ,
1 (0.8)	4 (<1)
3 (2.5)	21 (1.3)
0	3 (<1)
2 (1.7)	33 (2.1)
3 (2.5)	7(<1)
1 (0.8)	2(<1)
, ,	` ,
36 (29.75)	245 (15.5)
	Radiotherapy (%) 121 22 (18.2) 10 (8.3) 1 (0.8) 1 (0.8) 3 (2.5) 0 2 (1.7) 3 (2.5) 1 (0.8)

TE, tissue expander.

^{*}p < 0.05, Pearson χ^2 test.

who subsequently went on to complete nippleareola complex reconstruction was, however, significantly lower in the irradiated cohort (Table 2).

Saline implants were used in 54.2 percent of patients in the irradiated cohort and 67.4 percent of patients in the nonirradiated cohort (p = 0.06, chi-square test). Mean final implant size was not significantly different between the two cohorts (Table 2).

Capsular Contracture

The distribution of the capsular contracture grade and the distribution of the postoperative aesthetic grade are reported in Figures 1 and 2. Overall, the distribution of capsular contracture grade was higher in the irradiated cohort than in the nonirradiated cohort (p=0.02, Mann-Whitney Utest) (Table 3 and Fig. 1). Specifically, however, although the incidence of grade III/IV contracture formation in the irradiated cohort (10.6 percent) was slightly higher than in the nonradiated cohort (6.3 percent), this difference was not significantly different (p=0.2, Fisher's exact test) (Figs. 3 through 5).

Aesthetic Results

Ninety-eight percent of patients in the irradiated cohort, and 95.5 percent of the patients in the nonirradiated cohort had an overall aesthetic result graded as good or excellent (p > 0.05) (Table 4; Figs. 6 and 7). There was a significant difference in the distribution of aesthetic grade between the irradiated and nonirradiated patients. That is, proportionally more

irradiated patients had good or very good results, whereas more nonirradiated patients had proportionally more excellent results (p = 0.039, Mann-Whitney U test) (Fig. 2).

Revisionary Procedures

Revisionary procedures were categorized in the following way: redo tissue expander, revision permanent implant, and need for salvage flap (latissimus dorsi or transverse rectus abdominis musculocutaneous flap). Slightly more patients in the nonirradiated groups required revision of their permanent implant (<1 percent versus 7 percent). There were no differences in the number of patients requiring new tissue expanders or the need for a salvage flap (Table 5).

Patient Satisfaction

Eighty-four percent of patients in the irradiated cohort and 90 percent of patients in the non-irradiated cohort said that they were satisfied with the result overall (p > 0.05). Ninety-two percent of patients in the irradiated cohort and 95 percent of patients in the nonirradiated cohort said that they would undergo the same procedure for breast reconstruction again (p > 0.05).

DISCUSSION

This series, representing an accumulation of over a decade of experience, illustrates that selected patients who require salvage mastectomy can successfully complete immediate tissue expander/implant reconstruction. The assessment of early complications in 1699 tissue expander/

Table 2. Key Demographics

	Prior Radiotherapy (%)	No Radiation History (%)	þ
Demographic data		· · · ·	
No. of patients	48	647	
Mean age, yr*	52.0	48.2	0.01
Mean BMI, kg/m ²	24.1	23.7	NS
Obese (BMI $\gtrsim 30 \text{ kg/m}^2$)	2 (4.3)	57 (9.1)	NS
Preoperative bra cup size	,	,	NS
A	9 (20.5)	93 (15.1)	
В	18 (40.9)	273 (44.3)	
C	10 (22.7)	166 (26.9)	
D	4 (9.1)	63 (10.2)	
>DD	2 (4.5)	16 (2.6)	
Reconstruction data	, ,	, ,	
Bilateral reconstruction	23 (47.9)	285 (44.1)	NS
Permanent implant size >500 cc	14 (29.2)	190 (29.5)	NS
Implant type: saline	23 (52.3)	407 (66.1)	NS
Completed reconstruction of breast mounds	100%	100%	NS
Mean time to exchange	195 days	202 days	NS
Completed NAC reconstruction*	8 (16.7)	298 (46.1)	< 0.001

BMI, body mass index; NS, not significant; NAC, nipple-areola complex.

^{*}p < 0.05, Pearson χ^2 , Fisher's exact, or t tests where appropriate.

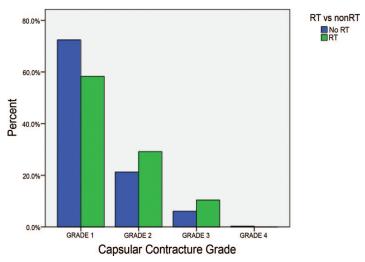


Fig. 1. Distribution of capsular contracture grade in patients with and without a history of prior irradiation (p = 0.02, Mann-Whitney U test).

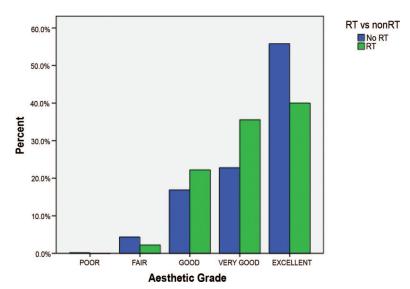


Fig. 2. Distribution of aesthetic grade in patients with and without a history of irradiation (p = 0.04, Mann-Whitney U test). RT, radiation therapy.

Table 3. Capsular Contractures in Patients with and without a History of Irradiation

	Prior Radiotherapy (%)	No Radiation History (%)*	Total (%)
No. of patients	48	645	693
Capsular contracture grade			
İ	28 (59.6)	467 (72.3)	496 (71.6)
2	14 (29.8)	137 (21.2)	151 (21.8)
3	5 (10.6)	39 (6)	44 (6.3)
4	0	2 (0.3)	2 (0.3)

^{*}p = 0.026 for prior radiotherapy versus no radiation history, Mann-Whitney U test.

implant reconstructions shows that although the early complication rate is higher in the previously irradiated patients compared with the nonirradiated patients (29.8 percent versus 15.5 percent; p

> 0.001), it is still within an acceptably low range. Moreover, the proportion who successfully completed reconstruction of the breast mound was similar in both groups, and good to excellent aes-

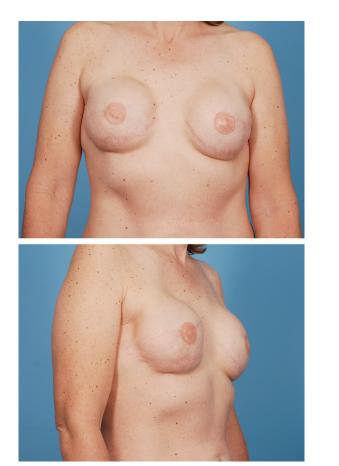


Fig. 3. Grade II capsular contractures in a previously irradiated patient (right breast previously irradiated).

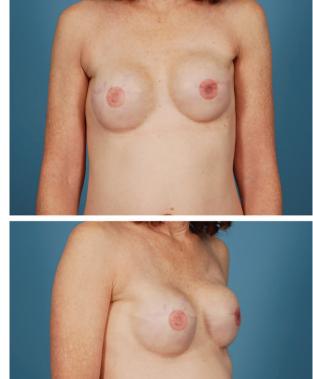


Fig. 4. Grade III capsular contractures in a previously irradiated patient (right breast previously irradiated).

thetic results were achieved in the majority of patients in both patient populations.

When looking at only those women who had been previously irradiated (and excluding all other patients from the reviews), many earlier reports of implant-based reconstruction in women that had been previously irradiated demonstrated unacceptably high rates of perioperative complications, ranging from 40 to 70 percent^{1,5–12} (Table 6). However, these studies suffer from very low patient numbers (three to 35 patients). The vast majority of these earlier articles that discuss reconstruction of previously irradiated patients consist of groups that are extremely heterogeneous (e.g., one-stage reconstruction, preoperative and perioperative radiation therapy, elective latissimus dorsi reconstruction). The generalized conclusions made by these articles do not apply to the specific groups of patients being reviewed in this article. Also, four of these six studies review patients treated in the 1970s and 1980s, when devices, techniques, and radiation protocols were much different from what they are

today. ^{1,5,6,8} One of these series, published by Evans et al., ⁵ excluded tissue expanders as part of the reconstruction, which also may explain their high extrusion rate (40 percent) in the perioperative period. Lastly, many of these series did not focus specifically on salvage mastectomy patients undergoing immediate reconstruction—they also included patients who were undergoing delayed reconstructions. ^{1,6,7}

In addition to the high incidence of early complications reported previously, concern has been raised regarding the incidence of late complications and poor aesthetic results in previously irradiated patients undergoing tissue expander/implant reconstruction. Previous reviews have reported grade III/IV capsular contracture rates in the previously irradiated population between 38 and 60 percent. ^{5,6,13,14} Kraemer et al. ¹¹ reviewed 35 previously irradiated patients undergoing delayed, unilateral tissue expander/implant reconstruction. In their series, 43 percent developed capsular contractures requiring capsulotomy. However, they pointed out that these rates were





Fig. 5. Grade IV capsular contracture and poor aesthetic result in a previously irradiated patient.

biased, as their tendency in practice is to perform autologous reconstructions on previously irradiated patients unless the patient has a contraindication to autologous reconstruction, or they refuse autologous reconstruction. Therefore, the patients undergoing tissue expander/implant reconstruction in this series had a high incidence of diabetes, smoking, and other major comorbidities predisposing them to complications. Their conclusion was that with careful patient selection, tissue expansion offers a simple, safe, and reliable method of breast reconstruction for patients who have been previously irradiated.

This current series shows that the majority of previously irradiated patients have an acceptably low rate of capsular contracture. Although capsular contracture grade was higher in the previously irradiated patients than in the nonirradiated patients (p = 0.02, Mann-Whitney U test), the incidence of grade III or IV capsular contracture was not significantly different (10.6 percent versus 6 percent; p = 0.2).

The majority of irradiated patients in this series had a good to excellent aesthetic result at a mean follow-up of 3.9 years. Previous authors have suggested that the aesthetic outcome is inferior in previously irradiated patients. Spear and Onyewu included 13 patients who had tissue expander/ implant reconstruction after previous lumpectomy/irradiation in their review and found that these patients had a lower mean aesthetic outcome score than the patients with no history of radiation therapy. 15 Ascherman et al. 9 also found an inferior overall aesthetic result in irradiated patients, but did not differentiate between those irradiated before reconstruction and those irradiated during reconstruction. The results of our study concur with these findings in that aesthetic grade in previously irradiated patients tended to be downgraded as compared with nonirradiated patients. However, the majority still had very acceptable (good to excellent) aesthetic results.

The need for revisionary procedures was not higher in the previously irradiated group of patients (2 percent versus 8 percent). This suggests that final results are acceptable for these patients. This is partly related to the fact that the threshold for revisionary procedures in this patient population is higher, as their risk for complications is higher. Despite this, patient satisfaction remains high among this patient population, as more than 90 percent of patients said that they would undergo this procedure again. High satisfaction and few revisionary procedures suggest reasonable success among a patient population where complication rates are higher and capsular contracture grade and aesthetic grade are less favorable. Addressing the patient's preoperative expectations plays a very important role in achieving these outcomes.

The results of this current experience suggest that tissue expander/implant reconstruction is a safe and reliable option for breast reconstruction in highly selected patients following salvage mastectomy. It is important to note that previously irradiated patients must be carefully selected before being considered as potential candidates for tissue expander/implant reconstruction. A careful clinical assessment of skin and soft-tissue quality should be performed. Patients may be considered for tissue expander/implant reconstruction if they have minimal to no discoloration of their skin from their previous irradiation. Clinically, their skin must still exhibit some elasticity. The soft tissues of the irradiated breast should feel normal to only slightly firm on palpation. In addition to assessment of the skin and soft-tissue

Table 4. Aesthetic Grade in Patients with and without a History of Irradiation

Aesthetic Outcome	Prior Radiotherapy (%)*	No Radiation History (%)*	Total (%)
No. of patients	48	645	693
Excellent, very good, or good	47 (97.9)	616 (95.5)	663 (95.7)
Fair or poor	1 (2.1)	29 (4.5)	30 (4.3)

^{*}p = 0.7, Fisher's exact test.



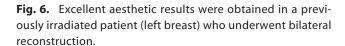






Fig. 7. Very good aesthetic results were obtained in a previously irradiated patient who underwent unilateral reconstruction.

quality, careful examination of previous breast scars is very important. Large or multiple scars on the irradiated breast may interfere with blood supply to the mastectomy flaps or may necessitate the removal of a large amount of skin during the reconstruction, which could lead to a tight closure over the prosthesis. Extra caution needs to be taken with elevation and handling of the mastectomy flaps to minimize complications. Care must also be taken with preoperative discussions; it is very important to help patients develop reasonable and appropriate expecta-

tions for the aesthetic outcome of their breast reconstruction.

Patients with worrisome skin and soft-tissue quality, unfavorable scars, or recent irradiation (<2 years) would likely not be appropriate candidates for tissue expander/implant reconstruction. These patients may require well-vascularized tissue, such as a latissimus dorsi flap, for their reconstruction. The outcomes we present in this series are in previously irradiated patients with all of the above-mentioned characteristics that favor successful outcomes.

Table 5. Revisionary Procedures in Patients with and without a History of Irradiation

Revisionary Procedure	Prior Radiotherapy (%)	No Radiation History (%)	Total (%)
No. of patients	48	645	693
Redo tissue expander	0 (0)	3 (0.5)	3 (<<1)
Revision of implant	1 (2)	49 (7.6)	50 (7.2)
Salvage flap	0	1 (0.1)	0 (<<1)

Table 6. Summary of Published Reviews, Listing Only Those Patients with a History of Irradiation Undergoing Implant Reconstruction, Excluding Elective Latissimus Dorsi Patients

First Author	Patient Series Reviewed	No. of Patients with Prior Irradiation	No. of Patients with Early Complications	Long-Term Results (Capsular Contractures, Rippling, Aesthetic Outcome)
Dickson Evans	1984–1986 1975–1994	10* 5† (implant reconstruction only; no TE)	7/10 (70%) 2/5 (40%) rupture or exposure of implant necessitating implant removal	Not reported 3/5 (60%) grade III/IV capsular contracture
Kraemer	1985–1991	35*	2/35 (6%) infection, 4/35 (11%) TE leak	15/35 (43%) developed capsular contractures requiring capsulotomy
Forman	1976–1993	9 (7† + 1* + 1†*)	4/9 (44%), 1 extrusion, 1 infection leading to implant removal, 2 unable to expand	4/8 (50%), 2 grade III/IV capsular contractures, 2 malpositions requiring revision surgery
Wickman	1990-1994	8†		3/8 (38%) developed capsular
Contant	1990–1995	15†	4/15 (27%)	contractures 9/15 (60%), grade III/IV capsular contracture
Spear	1990–1997	13		5/13 (38%) required LD flaps secondarily; also lower mean aesthetic score in preoperative RT vs. no RT
Krueger	1994–1999	10 (7 † + 3*)	6/10 (60%); 2/10 (20%) reconstruction failure rate	Not reported
Chawla	1981–1999	3†	High complication rate in patients with preoperative or postoperative RT (53%); timing of RT not important	Not reported
Ascherman	1996–2003	8†	No difference in complication rate between preoperative RT and perioperative RT group; overall RT total complication rate 40%	Inferior aesthetic outcome in RT vs. non-RT patients
Percec	2000–2007	7†	Compared complication rates according to timing of RT; majority of complications occurred in patients that had prereconstruction RT	20% > grade II capsular contractures
Persichetti	2003–2006	20†	75% had complications (25% minor, 50% major) vs. 49% in no-RT group	40% grade III/IV capsular contracture in RT group vs. 6.9% in no-RT group

TE, tissue expander; RT, radiation therapy; LD, latissimus dorsi.

CONCLUSIONS

Tissue expander/implant breast reconstruction should be considered an option for patients with previous chest wall irradiation who will be undergoing mastectomies. Candidates should be highly selected based on their tissue quality, location of previous scars, timing of irradiation, and patient expectations. In these highly selected patients, the success rate of tissue ex-

pander/implant breast reconstruction is acceptable but slightly inferior in previously irradiated compared with nonirradiated patients. Ultimately, these patients can expect to complete their breast reconstruction process and be satisfied with their final result. However, they can expect aesthetic results that are slightly inferior to those in patients who have not been previously irradiated. They can also expect a slightly

^{*}Delayed reconstruction.

[†]Immediate reconstruction.

higher rate of grade III or IV capsular contracture in the previously irradiated breast.

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