Prepectoral Implant-Based Breast Reconstruction with Postmastectomy Radiation Therapy

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Background: Two-stage subpectoral implant-based breast reconstruction is the most common method for breast reconstruction. Recent advances in surgical techniques and technology have made prepectoral implant-based breast reconstruction feasible. There are limited data on outcomes after prepectoral implant-based breast reconstruction and postmastectomy radiation therapy.

Methods: A retrospective review of consecutive patients undergoing immediate two-stage prepectoral implant-based breast reconstruction with postmastectomy radiation therapy was performed. Outcomes of irradiated breasts were compared with nonirradiated breasts in bilateral cases.

Results: Ninety-three cases of prepectoral implant-based breast reconstruction in 54 women who underwent immediate two-stage reconstruction (39 bilateral and 15 unilateral) and unilateral postmastectomy radiation therapy were identified. Mean follow-up was 19 months from mastectomy and tissue expander reconstruction and 9 months from implant placement. Crude complication rates in irradiated versus nonirradiated sides were as follows: surgical-site infection, 18.5 percent versus 7.7 percent; seroma, 5.6 percent versus 5.1 percent; mastectomy skin flap necrosis, 1.9 percent versus 2.6 percent; wound dehiscence, 1.9 percent versus 7.7 percent; capsular contracture, 1.9 percent versus 0 percent; hematoma, 1.9 percent versus 2.6 percent; and extrusion, 1.9 percent versus 0 percent. On univariate analysis, there were no risk factors associated with any complication, including radiation therapy, surgical-site infection, unplanned readmissions, and unplanned return to the operating room. To date, reconstruction has been completed in 96 percent of patients, with successful implant-based breast reconstruction in 81 breasts (45 irradiated breasts and 36 nonirradiated breasts).

Conclusions: Early data of prepectoral implant-based breast reconstruction in patients with postmastectomy radiation therapy show promising results. Postmastectomy radiation therapy should not be an absolute contraindication to prepectoral implant-based breast reconstruction. (*Plast. Reconstr. Surg.* 142: 1, 2018.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

Two-stage subpectoral implant-based reconstruction is the most common method for breast reconstruction.[1] The first description of prepectoral implant-based breast reconstruction was by Snyderman and Guthrie in 1971, with delayed placement of a breast implant.[2] Other early attempts at prepectoral implant-based breast reconstruction have been described but were ultimately abandoned, as muscle coverage of the implant was found to significantly reduce complications.[3] In 1991, Artz et al. described a successful 6-year experience with prepectoral tissue expansion; however, the reconstruction was performed with polyurethane-covered silicone implants, which were subsequently banned by the U.S. Food and Drug Administration.[4] Recent advances in surgical techniques and technology—including new-generation tissue expanders and breast

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implants, acellular dermal matrices, intraoperative flap perfusion analysis, and fat grafting—have allowed plastic surgeons to revisit the concept of prepectoral breast reconstruction.[5–27]

Subpectoral implant placement can lead to animation deformity and muscle spasms, which have been shown to improve after changing an implant to the prepectoral plane.[22,28,29] Thus, one would expect prepectoral implant-based breast reconstruction to be associated with a decreased incidence of animation deformity and muscle spasms. Other theoretical advantages of prepectoral implant-based breast reconstruction include a more natural appearing breast, reduced postoperative pain, and shorter operative times. These are directly related to the preservation of the pectoralis major muscle in its anatomical position.

In women with lymph node–positive breast cancer, postmastectomy radiation therapy reduces the risk of recurrence and improves overall survival.[30] However, postmastectomy radiation therapy also increases the risk of adverse cosmesis and reconstructive complications in women with implant-based breast reconstruction.[31] We present a single-institution experience with immediate two-stage prepectoral implant-based breast reconstruction and postmastectomy radiation therapy, which to our knowledge represents the first report discussing outcomes of prepectoral implant-based breast reconstruction in patients treated with postmastectomy radiation therapy.

PATIENTS AND METHODS

Patient Selection

After Mayo Clinic Rochester Institutional Review Board approval, we performed a retrospective review of consecutive patients from Mayo Clinic Rochester who underwent two-stage prepectoral implant-based breast reconstruction with postmastectomy radiation therapy from October of 2012 to December of 2016. Exclusion criteria included patients with less than 1-month follow up after final implant exchange, direct-to-implant breast reconstruction, planned autologous reconstruction, delayed reconstruction, and a history of radiation therapy to the chest before mastectomy and tissue expander placement. Demographics, comorbidities, and details of all surgical procedures were collected through review of the electronic medical records. Records were also reviewed for the following complications: surgical-site infection, defined as culture-proven infection and/or removal of the tissue expander or implant without immediate replacement within 1 year of tissue expander or implant placement according to the Centers for Disease Control and Prevention guidelines of surgical-site infection[32]; seroma, defined as a palpable fluid collection on clinical examination with or without imaging confirmation; mastectomy skin flap necrosis; wound dehiscence; capsular contracture (Baker grade III or IV); hematoma; and tissue expander or implant extrusion. The rates of unplanned readmissions, unplanned return to the operating room, and status of the tissue expander or implant after return to the operating room were obtained. Rates of local and distant recurrence and death were also recorded. Analysis of complications included both stages of reconstruction, because complications can occur after postmastectomy radiation therapy while the tissue expander remains in place and may require an alternative method of breast reconstruction.

Prepectoral Tissue Expander Breast Reconstruction Technique

Preoperatively, prepectoral versus subpectoral reconstruction options were discussed with the patient. The initial decision for tissue expander location was made based on patient and surgeon preference. The final decision was not made until mastectomy flap perfusion was assessed intraoperatively, either subjectively by palpation and visual inspection, or objectively by intraoperative fluorescence imaging using the SPY Elite system (Novadaq, Bonita Springs, Fla.). Use of intraoperative fluorescence imaging for objective assessment of the mastectomy skin flap perfusion varied based on surgeon preference. Tissue expanders were filled with air, and manually fenestrated acellular dermal matrices were used in nearly every case [most commonly, AlloDerm RTU (LifeCell Corp. Branchburg, N.J.), with Strattice (LifeCell) used in one patient with bilateral reconstruction]. One or two drains were placed in each mastectomy pocket, with an additional drain placed in the axilla in cases where an axillary lymph node dissection was performed. The tabs on the tissue expander were sutured to the underlying chest wall, and the skin was closed in a standard fashion. The final tissue expander fill volume was adjusted based on mastectomy skin flap perfusion assessment. All patients received preoperative antibiotic prophylaxis and continued antibiotics until all drains were removed.

Adjuvant Therapies

Tissue expansion with saline was initiated approximately 2 weeks postoperatively and completed by the time of the computed tomographic simulation for postmastectomy radiation therapy planning. In patients who did not undergo adjuvant chemotherapy, computed tomographic simulation typically occurred 6 weeks after the first-stage surgery such that postmastectomy radiation therapy could begin by postoperative week 8. In patients who underwent adjuvant chemotherapy, postmastectomy radiation therapy usually began 3 to 4 weeks after the final dose of chemotherapy.

The ipsilateral tissue expander was typically overinflated before postmastectomy radiation therapy planning to account for fibrosis and contraction from radiation. In cases of bilateral reconstruction, the contralateral expander was frequently deflated before postmastectomy radiation therapy planning to enable targeting of the internal mammary lymph nodes with a wide tangent technique while minimizing exposure to the contralateral reconstructed tissues.[33] The median radiation dose prescribed was 50 Gy in 25 fractions (range, 49 to 60 Gy in 25 to 30 fractions).

Implant Exchange

Silicone implant exchange was usually performed at least 6 months after completion of postmastectomy radiation therapy. All patients received preoperative antibiotic prophylaxis before surgery. The surgical procedure was typically performed using the same incision used for the mastectomy and first-stage reconstruction. Differences in incorporation of acellular dermal matrix between irradiated and nonirradiated breasts were not systematically assessed. Capsulotomies were performed as required. Drains were not routinely placed. Fat grafting was simultaneously performed in most cases to improve contour and/or mastectomy flap thickness. Figures 1 and 2 demonstrate patient results with this technique.

Statistical Analysis

Study data were collected and managed using REDCap (Nashville, Tenn.) tools hosted at Mayo Clinic Rochester.[34] Outcomes of irradiated

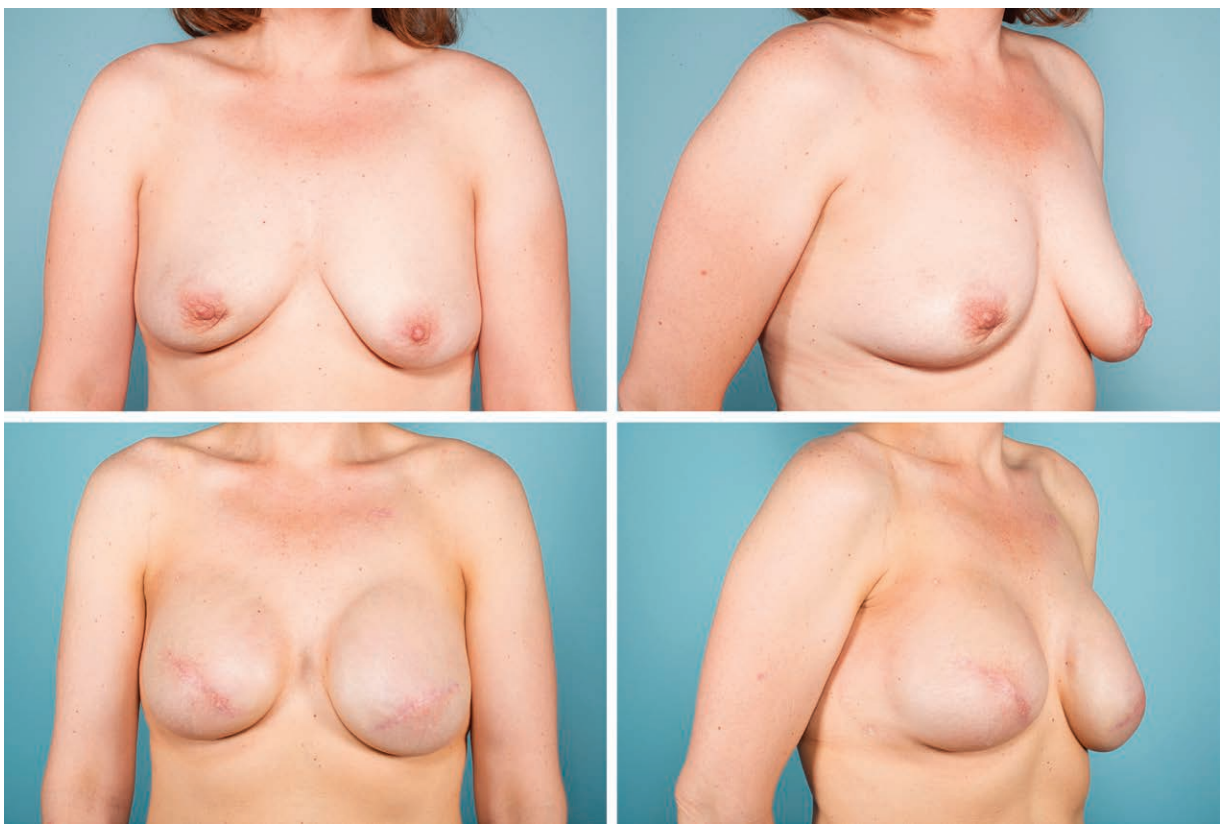

Fig. 1. Bilateral skin-sparing mastectomies and prepectoral implant-based breast reconstruction with postmastectomy radiation therapy to the right breast. Preoperative view (*above*) and postoperative view 10 months after completion of stage 2 implant exchange (*below*).

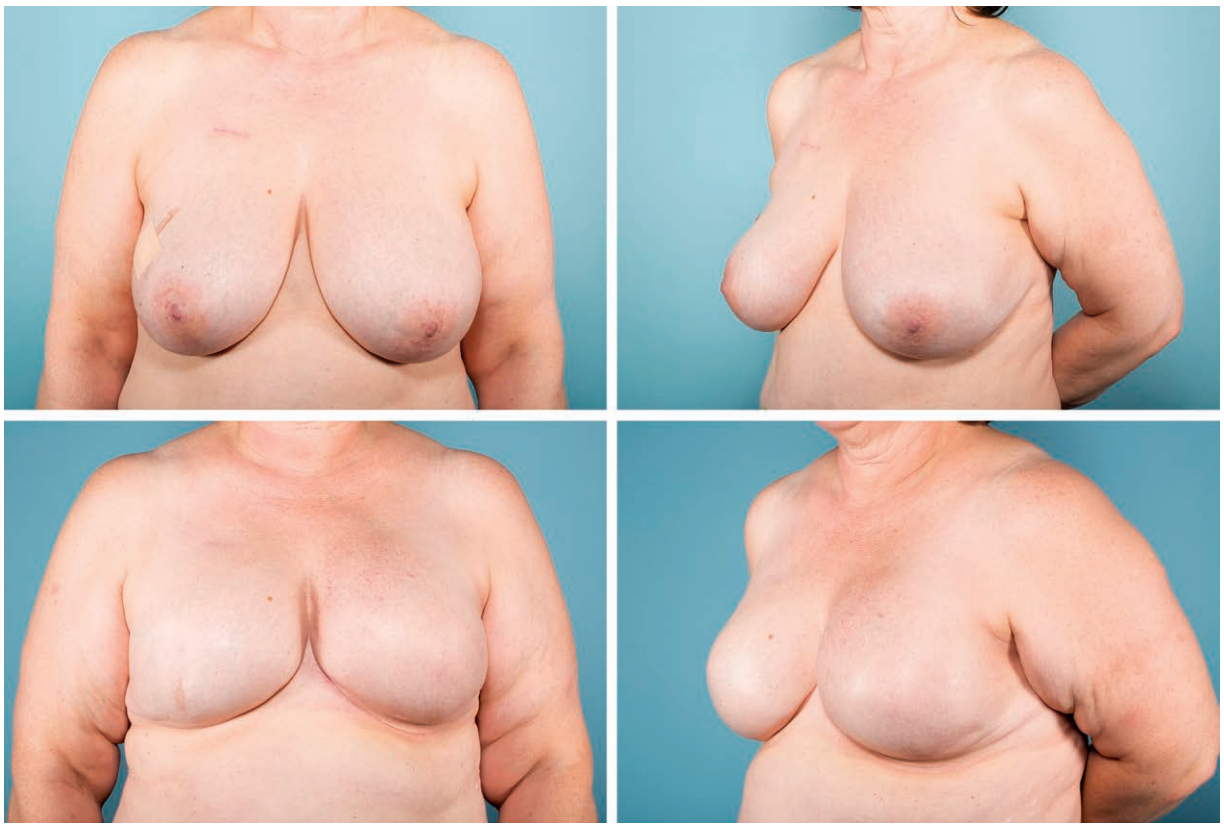

Fig. 2. Bilateral skin-sparing mastectomies with Wise pattern incision and prepectoral implant-based breast reconstruction with postmastectomy radiation therapy to the left breast. Preoperative view (*above*) and postoperative view 10 months after completion of stage 2 implant exchange (*below*).

breasts were compared with those of nonirradiated breasts in bilateral cases. Descriptive statistics were reported as number, percentage, or mean as appropriate. Kaplan-Meier survival was used to estimate the cumulative probability of outcomes with enough events, which included any complication, surgical-site infection, unplanned readmission, and unplanned return to the operating room. Univariate Cox models were used to assess the associations of patient, treatment, and technical factors with the risk of each of these four outcomes. The Cox model accounted for correlated sides within a patient. Multiple variable models were created for the two outcomes with at least 20 events, which included any complication and unplanned return to the operating room. These models looked at two variables at a time, radiation to the breast and a single additional variable, and examined whether the association of radiation to the breast was changed if an additional variable was included in the model. A value of $p < 0.05$ was considered statistically significant. The data were analyzed using the SAS Version 9.4 software package (SAS Institute, Inc., Cary, N.C.).

RESULTS

Patient Characteristics

Ninety-three cases of prepectoral implant-based breast reconstruction in 54 women (39 bilateral and 15 unilateral) who received unilateral postmastectomy radiation therapy were identified. Mean follow-up was 19 months from initial reconstruction (range, 1 to 36 months) and 9 months from implant exchange (range, 1 to 28 months). The average patient age was 48 years (range, 30 to 69 years). The average body mass index was 27.2 kg/m^2 (range, 19.4 to 40.7 kg/m^2). Patient characteristics and comorbidities are listed in Table 1.

Cancer Characteristics and Multimodality Therapies

Most patients had stage II or III breast cancer (Table 2). Forty-seven patients (87.0 percent) underwent chemotherapy, 57.4 percent underwent neoadjuvant chemotherapy only, 5.6 percent underwent both neoadjuvant and adjuvant chemotherapy, and 24.1 percent underwent adjuvant chemotherapy only. Fifty-three patients (96.4

Table 1. Patient Demographics and Comorbidities

	Value (%)
No. of patients	54
Age at first-stage surgery	
<30 years	0 (0)
30–39 years	16 (29.6)
40–49 years	11 (20.4)
50–59 years	20 (37.0)
60–69 years	7 (13.0)
>70 years	0 (0)
BMI	
<18.5 kg/m^2	0 (0)
18.5–24.9 kg/m^2	21 (38.9)
25–29.9 kg/m^2	20 (37.0)
30–34.9 kg/m^2	8 (14.8)
>35 kg/m^2	5 (9.3)
Tobacco use	
Current smoker	0 (0)
Former smoker*	14 (25.9)
Medical comorbidities	
Hypertension	9 (16.7)
Diabetes	0 (0)
Coronary artery disease	0 (0)
DVT/PE	3 (5.6)
Connective tissue disease	4 (7.4)

BMI, body mass index; DVT, deep venous thrombosis; PE, pulmonary embolism.
*All patients quit smoking at least 30 days before surgery.

Table 2. Cancer Characteristics and Multimodality Therapies

Characteristic	Value (%)
No. of patients	54
Cancer stage	
I	0 (0)
II	25 (46.3)
III	27 (50.0)
IV	2 (3.7)
Chemotherapy	
None	7 (13.0)
Neoadjuvant only	31 (57.4)
Neoadjuvant and adjuvant (before final implant)	2 (3.7)
Neoadjuvant and adjuvant (after final implant)	1 (1.9)
Adjuvant only (before final implant)	13 (24.1)
Radiation therapy timing	
Before final implant exchange (i.e., tissue expander irradiated)	53 (98.1)
After final implant exchange (i.e., final implant irradiated)	1 (1.9)

percent) had the tissue expander in place at the time of postmastectomy radiation therapy, and one patient had implant exchange performed 18 days before postmastectomy radiation therapy.

The average time from the first-stage surgery to postmastectomy radiation therapy in patients who did not receive adjuvant chemotherapy was 50 days (range, 34 to 71 days). The average time from the end of adjuvant chemotherapy to the start of postmastectomy radiation therapy was 35 days (range, 20 to 56 days).

Operative Characteristics

The types of oncologic resection and reconstruction are detailed in Table 3. Two patients had a delayed contralateral prophylactic mastectomy with immediate tissue expander placement after their initial oncologic procedure and implant-based breast reconstruction (included in the 39 patients with bilateral reconstruction). One patient underwent fat grafting before second-stage surgery for radiation-induced skin changes.

The average time to completion of reconstruction, defined by the number of days between tissue expander placement and implant placement, was 332 days (range, 110 to 783 days). Thus far, reconstruction has been completed in 88 breasts (96 percent of patients, excluding one patient who died as a result of metastatic disease before second-stage reconstruction), 51 irradiated breasts and 37 nonirradiated breasts (Table 4). Two patients have not yet completed their reconstruction; both required tissue expander explantation, one for surgical-site infection after completing postmastectomy radiation therapy and the other for mastectomy skin flap necrosis. For the patients who have completed their second-stage surgery, a permanent silicone implant was placed in 49 irradiated breasts and 37 nonirradiated breasts. Unplanned unilateral autologous reconstruction was performed in two patients who had undergone tissue expander explantation for surgical-site infection. Additional procedures including fat grafting (into the mastectomy skin flap), capsulotomy, plication of the acellular dermal matrix pocket, scar revision, and reinforcement with additional acellular dermal matrices were performed in conjunction with the second-stage surgery in many of the patients. Mastectomy skin flap thickness was variable, but fat grafting was successfully performed even when the mastectomy skin flaps were found to be thin.

Fourteen reconstructed breasts had nipple reconstruction by means of nipple-areola complex tattooing and/or surgical creation of the nipple (23.7 percent of skin-sparing mastectomies, eight irradiated and six nonirradiated). Sixteen patients underwent additional procedures beyond their second-stage surgery; the most common procedures included fat grafting, scar revision, implant exchange, and symmetry procedures. More than one fat grafting procedure was performed in nine irradiated breasts (16.7 percent) and seven nonirradiated breasts (17.9 percent), with at most four episodes in one patient.

Table 3. First-Stage Surgery

	No. of Irradiated Breasts	No. of Nonirradiated Breasts	Total No. of Breasts
No.	54	39	93
Oncologic procedure			
Nipple-sparing mastectomy	18 (33.3)	16 (41.0)	34 (36.6)
Skin-sparing mastectomy	35 (64.8)	22 (56.4)	57 (61.3)
Areola-sparing mastectomy	1 (1.9)	1 (2.6)	2 (2.2)
Reconstructive procedure			
Immediate expander	54 (58.1)	37 (39.8)	
Delayed prophylactic mastectomy with immediate expander		2 (2.2)	
Reconstructive adjuncts			
Wise pattern	8 (14.8)	8 (20.5)	16 (17.2)
Mastopexy	1 (1.9)	1 (2.6)	2 (2.2)
Acellular dermal matrix	53 (98.1)	38 (97.4)	91 (97.8)

Table 4. Second-Stage Surgery

	No. of Irradiated Breasts (%)*	No. of Nonirradiated Breasts (%)*	Total No. of Breasts (%)*
No.	53	38	91
Completed	51 (96.2)	37 (97.4)	88 (96.7)
Permanent implant	49 (96.1)	37 (100)	86 (97.7)
Flap	2 (3.9)	0 (0)	2 (2.3)
Planned	0 (0)	0 (0)	0 (0)
Unplanned	2 (100)	0 (0)	2 (100)
Reconstructive adjuncts			
Fat grafting	42 (82.4)	31 (83.8)†	73 (83.0)
Capsulotomy	35 (68.6)	25 (67.6)	60 (68.2)
Scar revision	0 (0)	1 (2.7)	1 (1.1)
ADM plication	4 (7.8)	11 (29.7)	15 (17.0)
Addition of ADM for reinforcement	11 (21.6)	4 (10.8)	15 (17.0)

ADM, acellular dermal matrix.
*Excludes one patient with bilateral reconstruction who died before second-stage reconstruction.
†Three additional patients had fat grafting for symmetry in a nonirradiated breast where a mastectomy had not been performed.

Complications

The crude overall complication rate was 24.7 percent (23 breasts, 20 patients); the rate of complications was 25.9 percent (14 breasts) in irradiated breasts and 23.1 percent (nine breasts) in nonirradiated breasts (Table 5). Specific complication rates in irradiated versus nonirradiated breasts were as follows: surgical-site infection, 18.5 percent versus 7.7 percent; seroma, 5.6 percent versus 5.1 percent; mastectomy skin flap necrosis, 1.9 percent versus 2.6 percent; wound dehiscence, 1.9 percent versus 7.7 percent; capsular contracture, 1.9 percent versus 0 percent; hematoma, 1.9 percent versus 2.6 percent; and extrusion, 1.9 percent versus 0 percent. Seroma, mastectomy skin flap necrosis, and hematoma more commonly occurred while the tissue expander was in place, whereas surgical-site infection, capsular contracture, and extrusion more commonly occurred after implant exchange. Wound dehiscence was similarly distributed between the tissue expanders and implants. In the irradiated breasts, the majority of complications occurred after postmastectomy radiation therapy; however, two of five infections, two of three seromas, and the single mastectomy skin flap necrosis occurred while the tissue expander was in place before postmastectomy radiation therapy. The median time to any complication in an irradiated breast was 195 days versus 54 days in a nonirradiated breast.

Unplanned readmission occurred in 13 patients (24.1 percent) for complications on the irradiated breast versus four patients (10.3 percent) for complications on the nonirradiated breast, with the most common reason for readmission being surgical-site infection (Table 5). Unplanned return to the operating room was required in 16 irradiated breasts (29.6 percent) versus seven nonirradiated breasts (17.9 percent). The most common reason for reoperation was surgical-site infection, followed by seroma, wound dehiscence, hematoma, mastectomy skin flap necrosis, and extrusion. On the irradiated side, 11 of 13 unplanned readmissions (84.6 percent)

Table 5. Crude Number of Complications in Prepectoral Implant-Based Breast Reconstruction

	Irradiated Breast (%)	Nonirradiated Breast (%)
No.	54	39
Any complication*	14 (25.9)	9 (23.1)
Unplanned readmission	13 (24.1)	4 (10.3)
Tissue expander	7 (53.8)	2 (50.0)
Before PMRT	2 (28.6)	
After PMRT	5 (71.4)	
Implant	6 (46.2)	2 (50.0)
Unplanned return to OR	16 (29.6)	7 (17.9)
Tissue expander	9 (56.3)	3 (42.9)
Before PMRT	3 (33.3)	
After PMRT	6 (66.7)	
Implant	7 (43.8)	4 (57.1)
SSI	10 (18.5)†	3 (7.7)
Tissue expander	5 (45.5)	1 (33.3)
Before PMRT	2 (40.0)	
After PMRT	3 (60.0)	
Implant	6 (54.5)	2 (66.7)
Seroma	3 (5.6)	2 (5.1)
Tissue expander	3 (100)	2 (100)
Before PMRT	2 (66.7)	
After PMRT	1 (33.3)	
Implant		
Mastectomy skin flap necrosis	1 (1.9)	1 (2.6)
Tissue expander	1 (100)	1 (100)
Before PMRT	1 (100)	
Implant		
Wound dehiscence	1 (1.9)	3 (7.7)
Tissue expander		2 (66.7)
Implant	1 (100)	1 (33.3)
Capsular contracture: grade III or IV	1 (1.9)	0
Hematoma	1 (1.9)	1 (2.6)
Tissue expander	1 (100)	1 (100)
After PMRT	1 (100)	
Implant		
Extrusion	1 (1.9)	0
Tissue expander		
Implant	1 (100)	

PMRT, postmastectomy radiation therapy; OR, operating room; SSI, surgical-site infection.
*Number of patients with at least one complication (some patients had multiple complications).
†One patient had a surgical-site infection in both a tissue expander and an implant.

and 13 of 16 unplanned returns to the operating room (81.3 percent) occurred after postmastectomy radiation therapy. Nine devices (16.7 percent) were nonelectively explanted in irradiated breasts, and two (5.1 percent) were nonelectively explanted in nonirradiated breasts. Thus, implant-based breast reconstruction has been successful in 81 breasts (89 percent), 45 irradiated breasts (85 percent) and 36 nonirradiated breasts (95 percent). There were no local recurrences during the follow-up period, and distant disease occurred in six patients (11.1 percent). There were two deaths, both secondary to metastatic disease. A summary of the patients' clinical course and outcomes can be found in Figure 3.

Kaplan-Meier survival was used to estimate the cumulative probability of outcomes including any complication, surgical-site infection, unplanned readmission, and unplanned return to the operating room (Figs. 4 and 5). Univariate Cox models showed that none of the examined risk factors, including radiation therapy, significantly increased the risk of developing these outcomes (Table 6). Multiple variable models controlling for radiation therapy to the breast for any complication and unplanned return to the operating room showed the same results.

DISCUSSION

This study demonstrates slightly higher rates of overall complications in irradiated versus nonirradiated breasts following prepectoral implant-based breast reconstruction, although this was not statistically significant. The most notable difference is higher rates of surgical-site infection in irradiated breasts. Higher rates of mastectomy skin flap necrosis and wound dehiscence occurred in nonirradiated breasts; we believe this is likely justified by the small sample size in the present study. Unplanned readmissions, reoperations, and device explantations were more likely to result from irradiated breast complications. However, even with these complications, thus far, 85 percent of irradiated breasts have been successfully reconstructed with prepectoral implant-based breast reconstruction.

To date, published studies on prepectoral implant-based breast reconstruction have not focused primarily on outcomes in patients undergoing postmastectomy radiation therapy.[18–25] Published data on prepectoral, mostly nonirradiated implant-based breast reconstructions show an overall complication rate ranging from 0 to 24 percent. Individual complications and their prevalence include the following: surgical-site infection, 0 to 12 percent; seroma, 0.9 to 10 percent; skin or nipple necrosis, 0 to 6.8 percent; capsular contracture, 0 to 7.6 percent; hematoma, 0 to 4.3 percent; wound dehiscence, 0 percent; extrusion, 0 to 4.3 percent; implant dystopia, 0 to 0.8 percent; rippling, 0.6 percent; implant rupture, 5.6 percent; and explantation, 0 to 8 percent.[18–25] A systematic review assessing complication rates in all types of prepectoral implant-based breast reconstruction identified six studies with the following pooled complications: major infection, 1.2 percent; minor infection, 2.3 percent; seroma, 2.9 percent; hematoma, 2.3 percent; full nipple-areola complex necrosis, 1.1 percent; partial nipple-areola

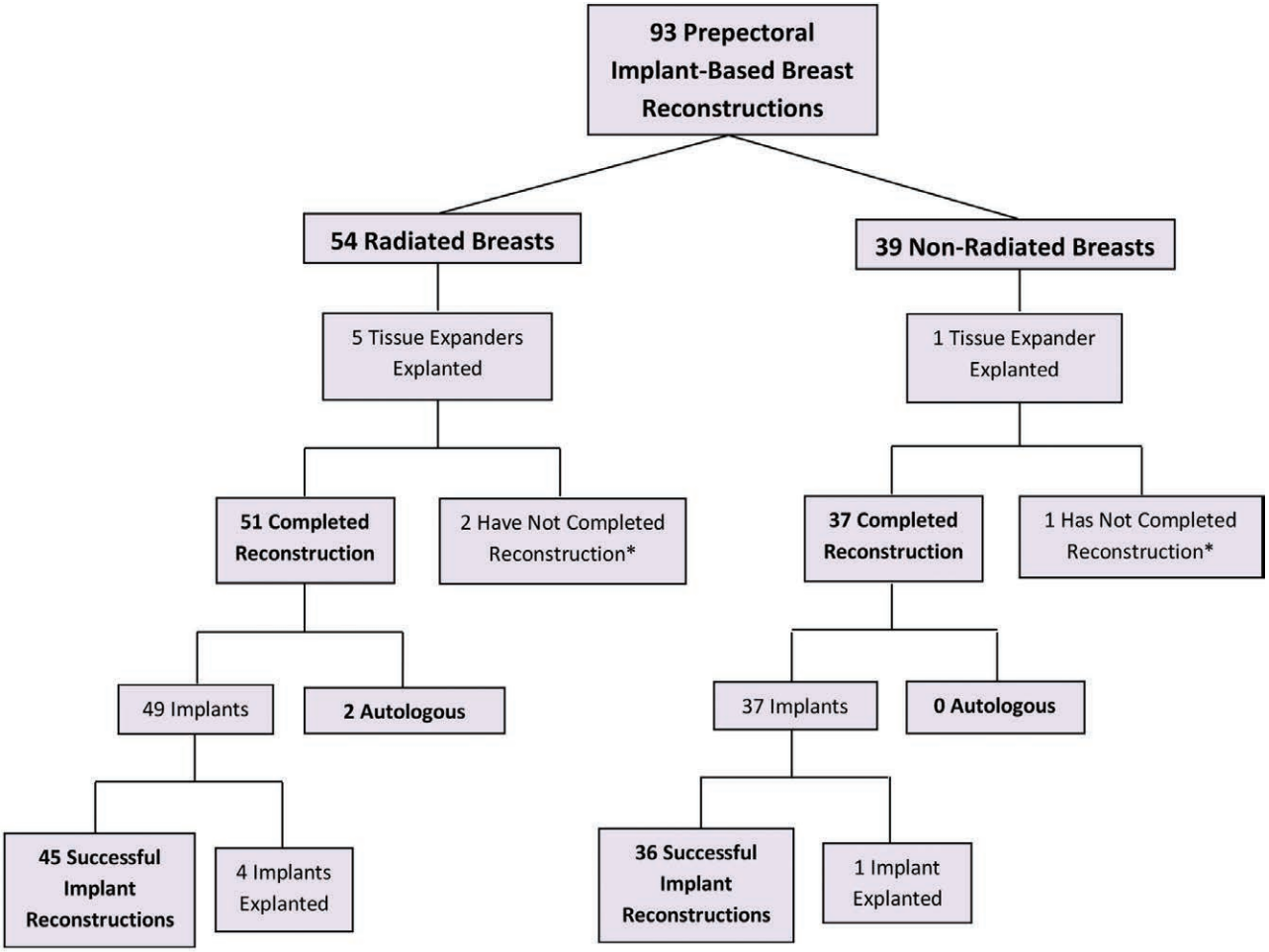

Fig. 3. Summary of clinical course and outcomes.

complex necrosis, 4.5 percent; major flap necrosis, 1.8 percent; wound healing complication, 2.3 percent; explantation, 4.1 percent; and grade III/IV capsular contracture, 1.2 percent.[35]

An earlier study from our institution looked at the first stage of breast reconstruction in the prepectoral plane and found greater intraoperative and first postoperative expansion volumes, shorter expansion duration, less pain during hospitalization, and fewer postoperative expansion visits compared with tissue expansion in the subpectoral plane. There was no difference in complications between the two methods; however, complications after implant placement were unable to be analyzed secondary to short follow-up.[18] Another study by Schnarrs et al. demonstrated a lower complication rate with prepectoral versus subpectoral implant-based breast reconstruction (19.7 percent versus 25.0 percent); however, this was not statistically significant because of the small sample size, and data were not available regarding the number of patients who underwent radiation therapy.[19]

There have been numerous studies evaluating the outcomes of patients undergoing subpectoral implant-based breast reconstruction and postmastectomy radiation therapy, including multiple systematic reviews. The most recent systematic review by El-Sabawi et al. analyzed surgical outcomes of patients undergoing implant-based breast reconstruction and adjuvant therapy, which included 3605 patients. At least 86.7 percent underwent two-stage breast reconstruction and at least 53.3 percent underwent radiation therapy to the tissue expander. The total complication rate was 41.3 percent, with individual complication rates as follows: surgical-site infection, 13.5 percent; seroma, 6.0 percent; skin or nipple necrosis, 10.5 percent; wound dehiscence, 5.8 percent; capsular contracture, 38.0 percent; hematoma, 2.8 percent; and

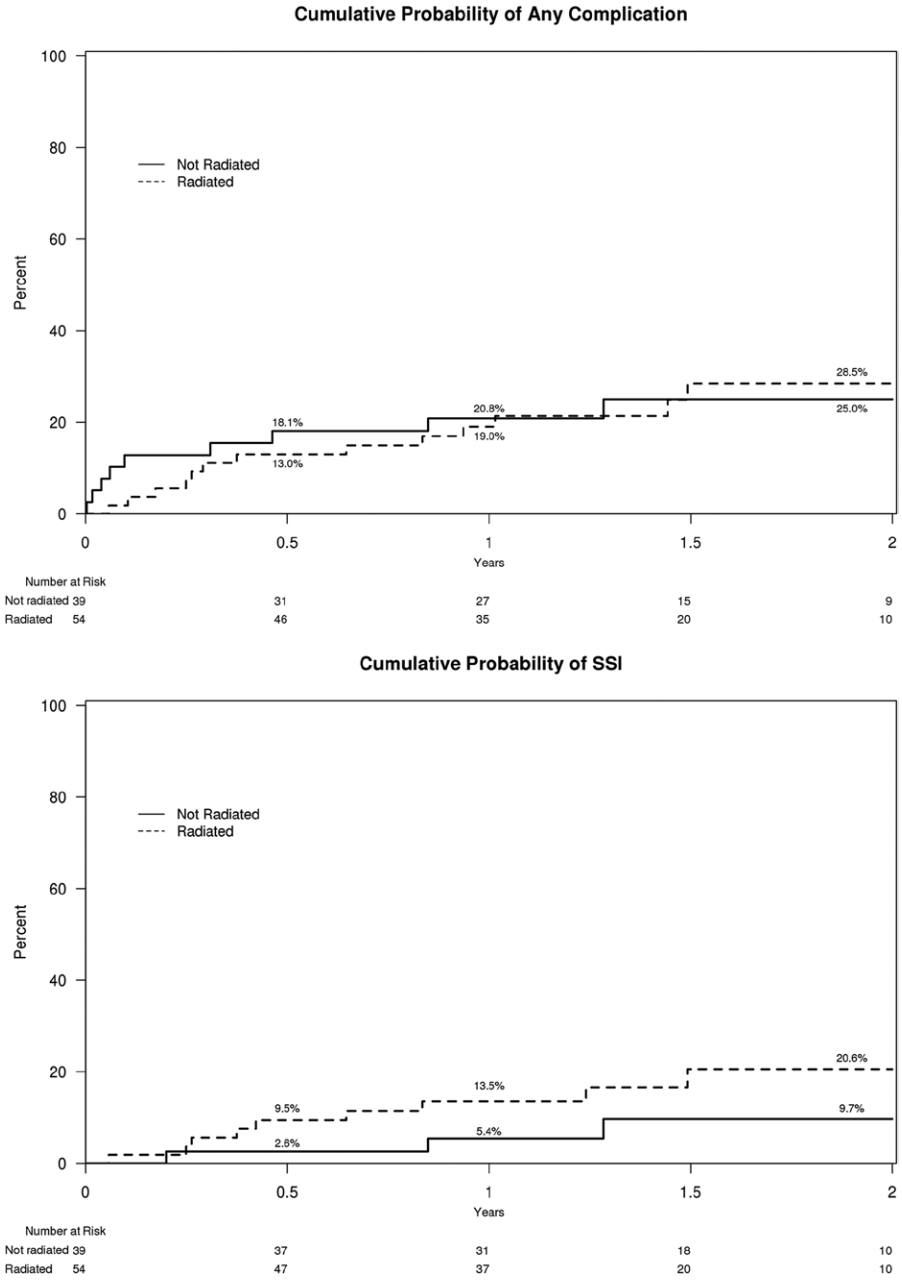

Fig. 4. Kaplan-Meier rates for the cumulative probability of any complication (*above*) and of surgical-site complication (*below*) in prepectoral implant-based breast reconstruction.

extrusion, 5.2 percent. The reoperation rate for complications was 37.0 percent and the reconstructive failure rate, defined as loss of the tissue expander or implant, was 16.8 percent.[36] Moreover, a recent prospective study assessing hypofractionated postmastectomy radiation therapy found a complication rate of 32 percent in reconstructed breasts with an implant failure rate of 24 percent that was attributable to postmastectomy radiation therapy.[37]

Using these historical data as a marker for comparison, outcomes in the present study compare favorably with subpectoral implant-based breast reconstruction in the setting of postmastectomy radiation therapy. We demonstrate lower rates of overall complications, capsular contracture, mastectomy skin flap necrosis, wound dehiscence, seroma, hematoma, extrusion, and reoperation and reconstructive failure. We show slightly higher surgical-site infection rates in the irradiated breasts, which is consistent with prior studies in subpectoral implant-based breast reconstruction with postmastectomy radiation therapy. This is likely because of the

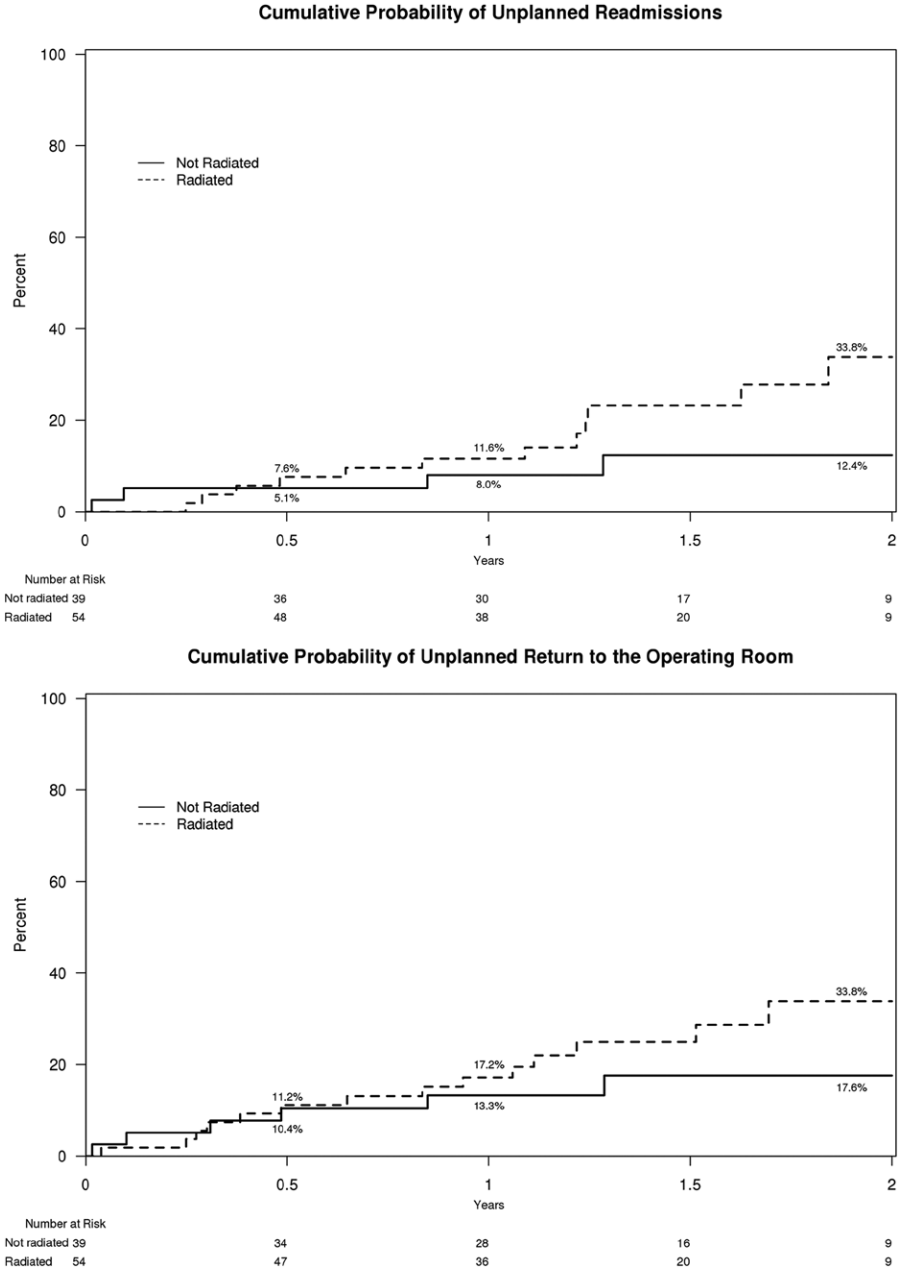

Fig. 5. Kaplan-Meier rates for the cumulative probability of unplanned readmission (*above*) and of unplanned returned to the operating room (*below*) in prepectoral implant-based breast reconstruction.

proximity of the tissue expander and implant to the external environment combined with radiation-induced skin changes that alter perfusion to the mastectomy flap. Given that this is a newly adopted technique, the learning curve for performing this technique and appropriately managing complications also likely contributes to this rate. In addition, there is significant heterogeneity in the definitions of surgical-site infection in the literature or an overall lack of defining criteria established in many publications, which makes comparisons between studies challenging. With the increasing focus on quality in health care, it is especially important that patient factors, such as postmastectomy radiation therapy, be considered as known risk factors for developing complications. Future studies should focus on factors and interventions that will help to decrease the surgical-site infection rate with this technique.

Table 6. Univariate Analysis for Risk Factors for Complications in Prepectoral Implant-Based Breast Reconstruction

	Any Complication		SSI		Unplanned Readmission		Unplanned Return to Operating Room	
Risk Factor	Hazard Ratio (95% CI)	*p*	Hazard Ratio (95% CI)	*p*	Hazard Ratio (95% CI)	*p*	Hazard Ratio (95% CI)	*p*
BMI								
25 to <30 kg/m^2	1.35 (0.50–3.65)	0.55	1.36 (0.45–4.12)	0.59	0.98 (0.35–2.70)	0.96	1.16 (0.41–3.29)	0.78
≥30 kg/m^2	1.47 (0.49–4.44)	0.49	0.89 (0.23–3.45)	0.86	0.47 (0.14–1.63)	0.24	1.11 (0.34–3.58)	0.86
Hypertension	1.08 (0.32–3.67)	0.90	1.04 (0.25–4.32)	0.95	1.32 (0.43–4.02)	0.62	1.41 (0.38–5.29)	0.61
History of tobacco abuse	0.83 (0.34–2.03)	0.69	0.69 (0.20–2.34)	0.55	0.65 (0.23–1.80)	0.41	0.91 (0.35–2.34)	0.84
Irradiation	1.09 (0.49–2.44)	0.83	2.65 (0.69–10.09)	0.15	2.56 (0.82–8.05)	0.11	2.03 (0.84–4.93)	0.12
Chemotherapy	0.80 (0.26–2.42)	0.69	0.37 (0.12–1.14)	0.08	0.89 (0.22–3.65)	0.88	0.70 (0.23–2.08)	0.52
Specimen weight ≥ 400 g	0.66 (0.28–1.59)	0.36	0.75 (0.27–2.08)	0.58	0.61 (0.24–1.52)	0.29	0.73 (0.30–1.79)	0.49
Mastectomy technique								
Nipple-sparing	1.73 (0.71–4.22)	0.23	2.06 (0.76–5.61)	0.16	1.21 (0.46–3.18)	0.71	1.05 (0.40–2.76)	0.92
Skin-sparing	0.52 (0.21–1.27)	0.15	0.37 (0.13–1.05)	0.06	0.69 (0.27–1.77)	0.44	0.83 (0.32–2.13)	0.69
Wise pattern	0.62 (0.15–2.58)	0.51	0.79 (0.19–3.25)	0.74	0.90 (0.32–2.56)	0.85	0.70 (0.16–3.10)	0.64
ADM	1.32 (0.07–23.49)	0.85	0.74 (0.04–14.23)	0.84	1.20 (0.06–22.61)	0.90	1.33 (0.07–24.02)	0.85
SPY angiography	0.44 (0.19–1.03)	0.06	0.83 (0.25–2.76)	0.76	1.24 (0.38–4.11)	0.72	0.48 (0.19–1.25)	0.13
Simultaneous fat grafting at second stage*	0.66 (0.14–3.14)	0.61	0.27 (0.06,1.15)	0.08	1.80 (0.21,15.24)	0.59	0.37 (0.13,1.11)	0.08

SSI, surgical-site infection; BMI, body mass index; ADM, acellular dermal matrix.
*Includes only complications that occurred after the second-stage surgery; remainder include all complications.

Another important element to consider is the aesthetic outcome. In theory, prepectoral implant placement will reduce animation deformity. However, without the additional layer of coverage that the muscle provides, there is a theoretical increased risk of implant visibility, palpability, and rippling. Many factors can influence this, including patient anatomy, mastectomy skin flap thickness, radiation-induced skin changes, type of implant selected, and performance of fat grafting. Our observation is that animation deformity is decreased and there is reduced breast asymmetry, as the implant is not located under the fibrotic, contracted, irradiated pectoralis major muscle.

Limitations of this study include the small sample size, retrospective design, and relatively short follow-up of 9 months after implant exchange. Certain complications in implant-based breast reconstruction—namely, capsular contracture—can take years to develop. Despite these limitations, we demonstrate that prepectoral implant-based breast reconstruction with postmastectomy radiation therapy has comparable, and in some cases improved, outcomes compared with subpectoral implant-based breast reconstruction with postmastectomy radiation therapy. Our group is planning on following this cohort of patients to determine long-term outcomes and also to analyze differences in outcomes between prepectoral and subpectoral implant-based breast reconstruction in patients undergoing postmastectomy radiation therapy.

CONCLUSIONS

Recent advances in surgical techniques and technology have stimulated a renewed interest in prepectoral implant-based breast reconstruction. This study is the first report of prepectoral implant-based breast reconstruction outcomes with postmastectomy radiation therapy. Our data show promising early results and a favorable complication profile. We found higher rates of complications in irradiated versus nonirradiated breasts, which is consistent with the published data on subpectoral implant-based breast reconstruction. Based on our findings, postmastectomy radiation therapy should not be a contraindication. Additional research is needed regarding this surgical technique, especially comparing long-term outcomes in prepectoral and subpectoral implant-based breast reconstruction in patients undergoing postmastectomy radiation therapy.

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