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Immediate Reconstruction of the Radiated Breast- Recent Trends Contrary to Traditional Standards

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Abstract

BACKGROUND—Immediate, implant-only breast reconstruction is traditionally discouraged in patients who receive radiation. It is not clear however, whether this widely-recognized mantra of breast reconstruction is observed in practice. The aim of this study is to evaluate reconstruction trends and practices in patients who have undergone mastectomy and radiation therapy.

METHODS—Female patients with unilateral breast cancer who required radiation in addition to mastectomy were extracted from the Surveillance, Epidemiology, and End Results (SEER) database from 2000 through 2010. Patients who underwent immediate reconstruction were identified and analyzed. Univariable and multiple logistic regression analyses were performed to study the odds of implant or combined implant-tissue reconstruction over tissue only reconstruction based on demographic and oncologic characteristics.

RESULTS—A total of 5,481 female patients who underwent radiation and breast reconstruction were included for analysis. The reconstruction rate among patients requiring radiation increased from 13.6% to 25.1%. The percentage of reconstructed patients who had implant only reconstruction increased from 27% to 52% ($p < 0.001$) with a decrease in tissue only reconstruction from 56% to 32% ($p < 0.001$); combined implant-tissue reconstructions remained stable at an average of 13%. In regression analysis, the odds of implant reconstruction over autologous reconstruction increased each year by an odds ratio of 1.13 (95% CI 1.10–1.15).

CONCLUSIONS—The frequency of immediate reconstruction continues to increase in the setting of radiation therapy with a larger proportion of patients undergoing immediate implant-based reconstruction, contrary to traditional recommendations. These findings likely reflect changing attitudes towards implant reconstruction in the setting of radiation.

LEVEL OF EVIDENCE—I

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Keywords

Immediate Breast Reconstruction; Radiation; National Trends; Surveillance; Epidemiology; and End Results

INTRODUCTION

Implant based reconstruction of the mastectomy patient has gained in favor in the United States in recent years¹. Immediate, implant-only breast reconstruction is however traditionally discouraged in patients who receive radiation therapy due to adverse tissue changes associated with radiation^{2–6}. These adverse tissue effects include tissue fibrosis, decreased vascularity, and increased tissue edema, ultimately portending a higher risk for postoperative morbidity including wound dehiscence, tissue expander exposure, and/or infection^{4,5,7}.

The significance of these tissue effects is underscored by multiple single-center studies with findings of relatively substantial morbidity associated with implant only breast reconstruction in the setting of radiation. Christante *et al* showed that implant removal was required in over 30% of patients who underwent immediate breast reconstruction followed by post-mastectomy radiation therapy (PMRT)⁴. Hirsch *et al* similarly reported a 50% complication rate in patients who undergo reconstruction *after* PMRT⁵. In spite of these findings, multiple studies in recent years have endorsed favorable outcomes of implant reconstruction of the radiated breast and this suggests that there may be a growing acceptance of this reconstructive approach^{8–10}. Implant reconstructions do provide distinct advantages including shorter operative times, less technically demanding operations, the avoidance of donor sites and potential for a shorter recovery relative to flap alternatives. These reasons in addition to better reimbursement for implant reconstruction have likely contributed to its overall increased use for breast reconstruction.

Current national reconstruction practices and trends specifically in the more challenging radiated patient are less well known. To gain a better understanding of the reconstructive management of patients requiring post-mastectomy radiation therapy this study aims to describe national trends for reconstruction of the radiated breast, and to assess factors that influence the reconstructive methods used.

METHODS

Data

Population-level de-identified data were extracted from the SEER cancer database (November 2012 submission) for the years 2000 through 2010. The SEER database collects patient-level data for all index malignant tumors in 18 cancer registries across the United States and captures 28% of the nation's population¹¹. This database is regarded as nationally representative and contains detailed demographic, socioeconomic, oncologic, and therapeutic information. To ensure data accuracy, chart abstracters undergo extensive training. Malignant tumors are encoded by use of the ninth revision of the International Classification of Diseases for Oncology. In addition to demographic and oncologic data, the

SEER database has recently included specific data on multiple breast reconstruction techniques. Data on reconstruction in this database is limited to procedures performed within 4 months of mastectomy. Thus, data on delayed reconstructions performed greater than 4 months after mastectomy was not available.

Patient Inclusion/Exclusion

Female patients aged 18 years to 80 years from 2000 to 2010 with American Joint Committee on Cancer (AJCC) stage I to III breast cancer were eligible for selection. Patients with a diagnosis of unilateral, ductal and/or lobular carcinoma (histology codes: 8500, 8501, 8503, 8504, 8520, 8521, 8522, 8523, 8524), who had undergone unilateral mastectomy (surgery codes 30, 40–75, 80) with radiation and specified reconstruction were included. Only patients with new primary breast cancers were included.

Statistical Analysis

Categorical demographic characteristics accounted for in our analysis included age (18–35, 36–55, 56–70, and 71–80 years old), race (White, Black, Other, Unknown), and year of diagnosis (2000–2010). Categorical oncologic variables included tumor stage (I, II, III), tumor size (< 1 cm, 1–1.9 cm, 2–4.9 cm, 5+ cm, unknown), tumor grade (I, II, III, IV), node status (positive, negative, unknown), ER status (positive, negative, unknown/borderline), PR status (positive, negative, unknown/borderline), radiation (yes, no, unknown), and whether this was a first primary (yes or no). Associations between characteristics and type of reconstruction were determined using Chi-square tests of independence for categorical associations and Kruskal-Wallis tests for continuous associations. A multinomial logistic regression model was developed to determine the odds of choosing implant alone over tissue reconstruction combined reconstruction over tissue reconstruction controlling for personal and tumor characteristics. All statistical analyses were performed with SAS version 9.3 (SAS Institute Inc.). Tests were deemed statistically significant at the level of 0.05.

RESULTS

Population Characteristics and Reconstruction Trends

A total of 40,568 patients who underwent mastectomy and radiation were identified over the 11-year period. Reconstruction was performed in 6,875 patients (16.9%). The reconstruction rate in radiated patients increased from 13.6% in 2000 to 25.1% in 2010 (Fig 1). Of these women with reconstruction, 5,481 (13.5%) patients had specific reconstruction surgery type information (implant, tissue, or both) and this manuscript focuses on this sample as shown in Table 1. A majority of the reconstructed patient population (88.6%) fell within an age range from 36 to 70 years. 2,760 patients (50.4%) had stage III breast cancers, with 4,444 patients (81.1%) having node positive disease. 5,390 patients (98.3%) were exposed to post-mastectomy radiation therapy. The demographic breakdown and tumor characteristics related to reconstruction method are outlined in Table 2. The percentage of specified reconstructed patients who were reconstructed with implants only increased from 29% in 2000 to 52% in 2010 (Fig 2); over the same time period the percentage of reconstructed patients reconstructed with autologous tissue generally decreased from 55% to 32%. The use

of combined autologous tissue with implant techniques remained relatively consistent with the highest rate of 19% in 2001 and lowest rate of 8% in 2009.

Association between demographic and tumor characteristics and reconstruction method

Univariable analysis showed a statistically significant difference in the percentage of patients who underwent implant, autologous, or combined reconstruction when stratified by race, year of diagnosis, tumor stage, tumor size, ER, and PR status (Table 2). In a multivariable model, Black patients were significantly less likely to receive implant reconstruction than autologous tissue when compared with White patients (O.R. 0.49, 95% C.I. 0.39–0.61) (Table 3). Black patients were also significantly less likely to receive combined reconstruction than tissue reconstruction (O.R. 0.73, 95% C.I. [0.54,0.99], Table 3). From 2001 to 2010, there was an increasing trend in the odds of implant-based reconstruction over autologous reconstruction; on average each year increased the odds of implant reconstruction with an odds ratio of 1.13 (95% CI 1.10–1.15).

DISCUSSION

In this study, we describe the reconstructive trends specifically in breast cancer patients who have received radiation therapy. By using the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) database, we are able to obtain data from a population representative of the entire United States. The SEER database reports breast reconstruction method (autologous, implant, or combined) within a 4-month period after initial mastectomy. This database has been used by previous studies to evaluate trends in immediate breast reconstruction – however these studies have not previously evaluated differences in breast reconstruction technique based on patient receipt of radiation therapy^{12–14}.

We found that overall, 17% (6,875) of patients who had undergone radiation were reconstructed by either autologous, implant, or combined techniques within 4 months of their mastectomy, between 2000 and 2010. However, there has been a nearly 2-fold increase in the overall reconstruction rate of radiated patients, rising from 14% in 2000 to 25% in 2010. This may represent a growing level of comfort among plastic surgeons with reconstruction in the setting of PMRT or may just reflect the overall increased frequency of immediate breast reconstruction. Previous studies using the SEER database have confirmed an increasing trend in immediate breast reconstruction among all patients independent of radiation status^{12–14}. Using the Nationwide Inpatient Sample, Albornoz *et al* have shown that implant reconstruction rates increased by 11% annually from 1998 to 2008 and that overall reconstruction rates increase by 5% annually¹⁵. Similar findings of increased implant use were reported in a recent study by Jagsi *et al* using the MarketScan database¹.

Interestingly, this trend of increased implant use is not limited to the non-radiated patient. Implant breast reconstructions in patients who required radiation increased by nearly 2-fold from 2000 (29%) to 2010 (52%). By 2010, the percentage of irradiated patients receiving implant reconstruction (52%) was higher than either autologous tissue (32%) or combined reconstruction (16%). This increase in implant-based reconstruction in the irradiated patients may again be part of a broader trend of increased implant-based reconstruction in all

mastectomy patients^{1,15–18}. However a review of the literature suggests that surgeons are more willing to perform immediate implant-based reconstruction in radiated patients. After evaluating a series of twelve patients with bilateral tissue expander/implant reconstruction with subsequent unilateral PMRT, McCarthy *et al* found that in spite of higher rates of capsular contracture of the radiated breast, aesthetic results were good to excellent and patient satisfaction was high⁹. They concluded that immediate tissue expander/implant reconstructions are an acceptable option for patients requiring PMRT. More recently Sbitany *et al* in evaluating the morbidity associated with immediate implant reconstruction in 580 patients undergoing nipple-sparing mastectomy with or without radiation found significantly higher infections (21.6% vs 13.1%) and expander/implant losses (18.75% vs 5.1%) in radiated patients¹⁰. They concluded that immediate implant reconstruction in the setting of pre- or post-mastectomy radiation is a safe operation. Complications associated with implant reconstruction of the radiated breast cannot be overlooked. Our systematic review of the literature evaluating outcomes of implant based reconstruction in the setting of PMRT found an overall major complication rate of 39% with rates ranging from 2 to 94%^{4,5,8,19–30}; pooled data from included studies showed a 20% reconstruction failure rate¹⁹. These findings indicate that though successful reconstruction can be achieved with implants alone in radiated patients, a significant number of complications and failures can also be expected. By using a validated instrument to learn from the patient's perspective, Alborno *et al* found that PMRT has a negative impact on quality of life and satisfaction following implant-based reconstruction³¹.

A reality of breast cancer treatment and reconstruction is that in a substantial number of cases, some of the information needed for treatment may not be available prior to the mastectomy. Because final pathology results are often not available for several days or even weeks after the mastectomy, the need for radiation based on lymph node status or margins may not be known at the time of an immediate breast reconstruction. As such patients may undergo immediate reconstruction following their mastectomy only to find out that PMRT is needed weeks later. In an attempt to address this problem in this subset of patients undergoing mastectomy with the possible need for PMRT, Kronowitz and colleagues introduced the concept of delayed-immediate breast reconstruction³². Tissue expanders are placed at the time of mastectomy and filled allowing time for review of permanent sections with decisions on the need for PMRT. Patients not requiring PMRT proceed with immediate implant reconstruction and patients requiring PMRT are allowed to complete radiation with the tissue expander in place, prior to further delayed reconstruction (possibly with implants). A problem with this strategy is that as many as 32% of breasts expanders exposed to radiation fail during the reconstruction process and require explantation²⁸. An alternative approach that allows for a better determination of the need for PMRT prior to mastectomy and immediate reconstruction is the pre-mastectomy sentinel lymph node biopsy (PM-SLNB)³³. This is the technique employed at our institution wherein the sentinel lymph node biopsy is performed days to weeks in advance of the mastectomy. Patients who have a positive sentinel lymph node will likely require radiation, and therefore are not offered immediate breast reconstruction with implants or autologous tissue.

A concomitant decrease in immediate autologous reconstructions in the radiated patient population was also observed. Though the SEER database collects information on breast

reconstruction up to 4 months after the initial mastectomy it is unlikely that it captures delayed reconstructions. Delayed reconstructions are typically performed after completion of adjuvant chemotherapy and PMRT which in combination could span a 6 month period after mastectomy, which falls out of the collection period for the database. A preference for delayed autologous reconstruction in the radiated breast would be consistent with traditional recommendations for reconstruction in this patient population⁴. The approach of delayed autologous reconstruction avoids exposure of flaps to the untoward effects of radiation. The magnitude of the effect of present day radiation on flaps is a subject of debate, with some suggestions that favorable outcomes can be achieved with immediate autologous reconstruction followed by PMRT³⁴.

Race and ethnicity had an impact on the reconstructive method employed. Relative to Caucasians, Black patients in our study had significantly less odds of receiving implant reconstruction in the setting of PMRT. Understanding that barriers to access exist, the reason for this observed difference in reconstruction strategy is unclear. Interestingly, we did not find associations between the method of reconstruction among patients with PMRT and other demographic or oncologic factors. It is possible that the lack of a relationship with other oncologic factors is because the need for radiation among all of our patients is an “equalizing” factor in their oncologic assessment.

This study has a number of limitations. We are only able to report on immediate breast reconstruction rates and methods based on the unique features of the SEER database. Information on delayed reconstruction beyond 4 months after mastectomy would be important to gain a full appreciation of reconstruction trends in the broader community. Decisions made on reconstruction type may be influenced by surgeon preference and financial consideration for reimbursement. These factors unfortunately cannot be evaluated using the SEER database. Also not included in the database are patient factors such as obesity, smoking history, previous surgical procedures that preclude autologous options and patient preferences. Nevertheless, we present data from a large, diverse patient population that gives some insight into current national trends for reconstruction of the radiated breast.

CONCLUSIONS

Our study demonstrates that across the nation, immediate implant reconstruction has increased among patients who require PMRT. These findings likely reflect a changing attitude towards implant reconstruction in the setting of radiation therapy. Given the large number of radiated patients who are undergoing this procedure, and the relatively limited data on the broader community, there is room for significant inquiry into complications, cosmetic outcomes, patient satisfaction, quality of life, and the economic impact of varying reconstructive approaches. The latter is particularly interesting as providers may soon be forced to limit and share total spending for the management of patient conditions such as breast cancer.

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Figure 1.
Immediate Breast Reconstruction Rate from 2000–2010 in Patients Requiring Radiation.
(6,875 reconstructions/40,568 women with BC)

Figure 2.
Reconstruction Rates by Method in Radiated Patients from 2000–2010 out of all specified reconstructions

Table 1

Characteristics of all Radiated Patients who were reconstructed (Tissue, Implant, Combined n=5,481)

Characteristic	N	%
Age, years		
18–35	515	9.4
36–55	3690	64.7
56–70		21.3
71–80	110	2.0
Race		
White	4704	85.8
Black	472	8.6
Native American	21	0.4
Asian American	257	4.7
Other	12	0.2
Unknown	15	0.3
Year of Diagnosis		
2000	362	6.6
2001	383	7.0
2002	317	5.8
2003	345	6.3
2004	401	7.3
2005	421	7.7
2006	469	8.6
2007	550	10.0
2008	669	12.2
2009	758	13.8
2010	806	14.7
Stage		
I	442	8.1
II	2279	41.6
III	2760	50.4
Tumor Size		
<1	367	6.7
1–1.9	992	18.1
2–4.9	684	12.5
5+	3345	61.0
Unknown	93	1.7
Grade		
I	501	9.1
II	2189	39.9
III	2453	44.8
IV	80	1.5

Characteristic	N	%
Unknown	258	4.7
Node		
Negative	1034	18.9
Positive	4444	81.1
Unknown	3	0.1
ER Status		
Negative	1204	22.0
Positive	4098	74.8
Borderline/Unknown	179	3.3
PR Status		
Negative	1751	31.9
Positive	3502	63.9
Borderline/Unknown	228	4.2
Radiation Timing		
Before Surgery	50	0.9
After Surgery	5390	98.3
Both before and after surgery	25	0.5
Intraoperative	3	0.1
Intraoperative with before and after surgery	0	0
Sequence unknown, but both surgery and radiation	13	0.2

Table 2

Characteristics by type of reconstruction

Characteristic	Implant (n=2,307)		Tissue (n=2,486)		Combined (n=688)		p*
	N	%	N	%	N	%	
Age, years							
18–35	239	10.4	226	9.1	50	7.3	0.09
36–55	1536	66.6	1676	67.4	478	69.5	
56–70	478	20.7	536	21.6	152	22.1	
71–80	54	2.3	48	1.9	8	1.2	
Race							
White	2030	88.0	2078	83.6	596	86.6	<0.0001
Black	138	6.0	276	11.1	58	8.4	
Native American	16	0.7	3	0.1	2	0.3	
Asian American	112	4.9	115	4.6	30	4.4	
Other	4	0.2	7	0.3	1	0.1	
Unknown	7	0.3	7	0.3	1	0.1	
Year of Diagnosis							
2000	104	4.5	200	8.0	58	8.4	<0.0001
2001	103	4.5	207	8.3	73	10.6	
2002	86	3.7	178	7.2	53	7.7	
2003	117	5.1	181	7.3	47	6.8	
2004	153	6.6	200	8.0	48	7.0	
2005	161	7.0	213	8.6	47	6.8	
2006	192	8.3	221	8.9	56	8.1	
2007	228	9.9	263	10.6	59	8.6	
2008	332	14.4	281	11.3	56	8.1	
2009	412	17.9	283	11.4	63	9.2	
2010	419	18.2	259	10.4	128	18.6	
Stage							
I	189	8.2	188	7.6	65	9.4	<0.0001
II	1057	45.8	962	38.7	260	37.8	

Characteristic	Implant (n=2,307)		Tissue (n=2,486)		Combined (n=688)		p*
	N	%	N	%	N	%	
Tumor Size							
III	1061	46.0	1336	53.7	363	52.8	
<1	146	6.3	176	7.1	45	6.5	<0.0001
1-1.9	448	19.4	426	17.1	118	17.2	
2-4.9	201	8.7	376	15.1	107	15.6	
5+	1486	64.4	1452	58.4	407	59.2	
Unknown	26	1.1	56	2.3	11	1.6	
Grade							
I	211	9.1	237	9.5	53	7.7	0.28
II	954	41.4	944	38.0	291	42.3	
III	1006	43.6	1150	46.3	297	43.2	
IV	31	1.3	37	1.5	12	1.7	
Unknown	105	4.6	118	7.8	35	5.1	
Node							
Negative	448	19.4	454	18.3	132	19.2	0.68
Positive	1858	80.5	2031	81.7	555	80.7	
Unknown	1	0.1	1	0.1	1	0.1	
ER Status							
Negative	492	21.3	565	22.7	147	21.4	<0.0001
Positive	1771	76.8	1822	73.3	505	73.4	
Borderline/Unknown	44	1.9	99	4.0	36	5.2	
PR Status							
Negative	719	31.2	819	32.9	213	31.0	0.0002
Positive	1523	66.0	1544	62.1	435	63.2	
Borderline/Unknown	65	2.8	123	5.0	40	5.8	
Radiation Timing							
Before Surgery	17	0.7	29	1.2	4	0.6	0.081
After Surgery	2275	98.6	2439	98.1	676	98.3	
Both before and after surgery	10	0.4	8	0.3	7	1.0	
Intraoperative	1	0.1	1	0.1	1	0.2	

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Characteristic	Implant (n=2,307)		Tissue (n=2,486)		Combined (n=688)		p*
	N	%	N	%	N	%	
Sequence unknown, but both surgery and radiation given	4	0.2	9	0.4	0	0	

Table 3

Results from multinomial regression model for odds of undergoing implant only and combined reconstruction versus tissue only

	Implant Only vs. Tissue		Combined vs. Tissue		Full Model p-value
	OR	95% CI	OR	95% CI	
Age, years					0.040
18–35	1.00	Referent			
36–55	0.85	0.69–1.04	1.25	0.91–1.74	
56–70	0.80	0.64–1.01	1.22	0.85–1.75	
71–80	1.12	0.72–1.75	0.68	0.30–1.53	
Race					<0.001
White	1.00	Referent			
Black	0.49	0.39–0.61	0.73	0.54–0.99	
Other	1.04	0.80–1.34	0.93	0.62–1.38	
Unknown	0.92	0.32–2.67	0.48	0.06–3.96	
Year of Diagnosis					<0.001
2000	1.00	Referent			
2001	0.93	0.66–1.30	1.19	0.80–1.77	
2002	0.91	0.64–1.30	1.01	0.66–1.54	
2003	1.22	0.87–1.70	0.87	0.57–1.35	
2004	1.39	0.98–1.95	0.78	0.49–1.22	
2005	1.3	0.96–1.88	0.71	0.45–1.12	
2006	1.55	1.11–2.15	0.80	0.52–1.24	
2007	1.57	1.14–2.16	0.73	0.47–1.12	
2008	2.04	1.49–2.78	0.63	0.41–0.98	
2009	2.61	1.92–3.55	0.72	0.47–1.10	
2010	2.85	2.10–3.88	1.59	1.08–2.36	
Tumor Stage					<0.001
I	1.00	Referent			
II	1.08	0.83–1.39	0.68	0.47–0.99	
III	0.82	0.63–1.06	0.68	0.47–0.99	
Tumor Size					0.19

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	Implant Only vs. Tissue		Combined vs. Tissue		Full Model p-value
	OR	95% CI	OR	95% CI	
<1	1.00	Referent			
1-1.9	1.33	1.01-1.74	1.20	0.80-1.80	
2-4.9	1.12	0.80-1.58	1.19	0.74-1.90	
5+	1.23	0.94-1.61	1.40	0.93-2.10	
Unknown	0.80	0.46-1.38	0.94	0.44-2.02	
ER Status					0.08
Negative	1.00	Referent			
Positive	1.02	0.88-1.17	1.01	0.82-1.25	
Borderline/Unknown	0.70	0.48-1.03	1.36	0.88-2.10	