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A Systematic Review of Complications of Implant-Based Breast Reconstruction with Pre-Reconstruction and Post-Reconstruction Radiation Therapy

Adeyiza O. Momoh, MD¹, Raouf Ahmed, BSc Hons², Brian P. Kelley, MD³, Oluseyi Aliu, MD³, Kelley M. Kidwell, PhD⁴, Jeffrey H. Kozlow, MD⁵, and Kevin C. Chung, MD MS⁶

¹Clinical Assistant Professor, Section of Plastic Surgery, Department of Surgery, The University of Michigan Health System

²Medical Student, Section of Plastic Surgery, Department of Surgery, The University of Michigan Health System

³Resident Physician, Section of Plastic Surgery, Department of Surgery, The University of Michigan Health System

⁴Research Assistant Professor, Department of Biostatistics, University of Michigan, Ann Arbor, MI

⁵Clinical Assistant Professor, Section of Plastic Surgery, Department of Surgery, The University of Michigan Health System

⁶Professor of Surgery, Section of Plastic Surgery, Department of Surgery, The University of Michigan Health System

Abstract

Background—The specific aim of this study was to conduct a systematic review of the literature to assess outcomes data on complications associated with implant-based breast reconstruction performed before or after chest wall radiation to assist in guiding the decision-making process for reconstruction of the radiated breast.

Methods—Studies from a PubMed search that met predetermined inclusion criteria were identified and included. Complications of interest were low and high grade capsular contractures, minor and major complications, reconstruction failure rates and reconstruction completion rates. Pooled complication rates were calculated.

Results—A total of 26 articles were included in the study after screening 1,006 publications, with 14 studies presenting data on pre-reconstruction radiation and 23 studies presenting data on post-reconstruction radiation. Complication rates evaluated in patients exposed to radiation prior to or after implant reconstruction were not significantly different. Reconstruction failure rates were similar at 19% and 20% for pre and post-reconstruction radiation patients respectively. Completion rates were similar at 83% and 80% for pre and post-reconstruction radiation patients respectively.

Conclusions—Review of the current literature suggests similar overall success and failure rates with pre-reconstruction and post-reconstruction radiation therapy exposure. Failure rates in both groups of patients are clinically significant when considering implant reconstruction in the setting of radiation.

Keywords

Breast Reconstruction; Implants; Radiation Therapy

INTRODUCTION

Implant-based breast reconstruction continues to be the leading form of breast reconstruction in the United States. The American Society of Plastic Surgeons reports over 76,000 implant-based breast reconstruction procedures in 2011 (1) comprising approximately 79% of all breast reconstruction procedures. Its popularity amongst surgeons stems from the relative ease of the procedure, and the limited time/resource requirements for implantation.

Increasing numbers of breast cancer patients require post-mastectomy radiation therapy as part of their cancer treatment. The effectiveness of implant-based breast reconstruction in the setting of radiation therapy has been called into question (2, 3). Published data on the outcomes of implant reconstruction of the radiated breast have been inconclusive and contradictory (4, 5); nevertheless some authors endorse implant reconstruction procedures in this setting by citing acceptable cosmetic results and patient satisfaction (6).

Postoperative complication rates following implant-based breast reconstruction are known to be higher in radiated breasts when compared to similar non-radiated breasts. Radiated breasts however are not entirely uniform as the time of delivery of radiation to the breast relative to the time of reconstruction varies. Patients who require radiation therapy either undergo radiation prior to reconstruction or after reconstruction has been initiated or completed. There is little to no conclusive evidence from clinical trials presenting outcomes on implant reconstruction with these variations in the times of radiation therapy exposure relative to reconstruction.

The aim of this study was to perform a critical appraisal of the available literature to evaluate complication data on implant-based breast reconstruction prior to and after chest wall radiation to help guide the decision making process for reconstruction of the radiated breast.

PATIENTS AND METHODS

Search Criteria

A thorough literature search was conducted using PubMed/MEDLINE in August of 2012 to identify all citations reporting outcomes of implant based breast reconstruction in the setting of radiation therapy. The search terms used were “immediate versus delayed breast reconstruction”, “breast reconstruction and radiation” and “delayed breast reconstruction and radiation”. Multiple authors independently examined the titles and abstracts of citations

and generated a list of articles for review. The studies were then assessed against predetermined inclusion and exclusion criteria (Table 1).

Data Abstraction

The data were extracted from studies satisfying the inclusion criteria and verified by multiple authors. Any disagreements were resolved by consensus. Variables extracted included: study design, patient demographics, method and timing of reconstruction relative to radiation therapy, mean follow-up time, and complication rates.

Capsular contracture was defined as mild (grades IA, B and II) or severe (grades III and IV) (7). Similar to published complication categories by Hirsch et al (8), we defined minor complications as complications managed without surgical intervention and major complications as complications requiring surgical intervention. Minor complication categories included grades I and II capsular contractures, seromas, potential infections treated with oral antibiotics, minor wound healing abnormalities, and minor mastectomy flap necrosis that heal spontaneously. Major complication categories included threatened implant exposure, wound dehiscence, loss of implant due to exposure, mastectomy skin loss, capsular contracture grades III and IV, hematoma, pain/tightness, injection port migration, deflation and infection leading to loss of implant. Complications were reported per breast reconstruction, with one breast reconstruction comprised of two operations in staged reconstructions using an initial tissue expander. As each operation on a breast had potential for complications, multiple complications could be recorded per breast. Reconstructions were considered failures if implants had to be taken out, replaced with flaps or revised with the addition of a flap. Reconstructions were considered successful and complete in patients who had an implant alone in place at the end of the follow-up period for each study.

Analyses

Our outcomes of interest included minor and major complication rates, rates of capsular contracture, flap failure and completion rates. It was not possible to conduct a meta-analysis model of these studies because outcomes of interest were not reported with a uniform standard and there was significant heterogeneity among studies in terms of design and patient characteristics. Furthermore, most of the studies in the review were case series and not comparative studies between pre-reconstruction and post-reconstruction radiated breasts. From extracted frequencies of the outcomes of interest and the number of breasts for each outcome, we report the rates and 95% confidence interval for each possible complication or completion rate using the variance-stabilizing Freeman-Tukey double arcsine transformation method. Overall estimates and 95% confidence intervals of each outcome of interest were pooled for studies according to whether reconstruction was performed pre or post radiation using a random effects meta-analysis of the Freeman-Tukey transformed proportions (Table 3). Variance between studies was estimated using the DerSimonian-Laird estimator with chi-square tests of heterogeneity for all outcomes of interest, supplemented by the descriptive measure of I^2 . I^2 is often used as a descriptive measure to represent the proportion of total variation in the estimates of treatment effects that is due to heterogeneity (difference between studies), rather than to chance. To explore comparisons between pre-reconstruction and post-reconstruction radiation therapy, we report the overall point

estimates of each complication rate with confidence intervals, even with significant heterogeneity. All quantitative analysis was performed in R using the meta and rmeta packages.

RESULTS

Study Retrieval and Characteristics

A total of 1006 citations were identified from our initial PubMed search (Fig 1). The application of predetermined inclusion and exclusion criteria resulted in 26 selected articles to be utilized for the study. A summary of study characteristics is included in Table 2.

Patient Characteristics

Patients included in this study were all treated with mastectomies for breast cancer. Pre-reconstruction radiation therapy was delivered prior to reconstruction predominantly for breast conservation therapy. Post reconstruction radiation therapy was delivered either after placement of tissue expanders or after implant placement.

Capsular Contracture

Ten of the included studies (8, 14, 18, 20, 21, 24–27, 30) reported on mild capsular contracture with rates ranging from 2 to 83 percent (27, 24). The pooled mild capsular contracture rate was 30 percent (95 percent confidence interval, 0 to 77 percent) in 98 breasts radiated prior to reconstruction versus 37 percent (95 percent confidence interval, 20 to 55 percent) in 672 breasts radiated after reconstruction. Eleven studies (8, 10, 13, 14, 18, 20, 23, 24, 26, 27, 30) reported on severe capsular contracture with values ranging from 13 to 67 percent (23, 8). The pooled severe capsular contracture rate was 25 percent (95 percent confidence interval, 10 to 45 percent) in 68 breasts radiated prior to reconstruction and 32 percent (95 percent confidence interval, 20 to 46 percent) in 818 breasts radiated after reconstruction.

Minor Complications

Seven studies (7, 8, 18, 21, 23, 25, 27) reported data on complications classified as minor with rates ranging from 0 to 47 percent (25, 21). The pooled rate of minor complications was 18 percent (95 percent confidence interval, 5 to 36 percent) in 150 breasts radiated prior to reconstruction versus 31 percent (95 percent confidence interval, 17 to 46 percent) in 246 breasts radiated after reconstruction.

Major Complications

Sixteen studies (7–11, 13, 15–17, 19, 21, 23, 25–27, 31) reported data on complications classified as major with rates ranging from 2 to 94 percent (25, 8). The pooled rate of major complications was 49 percent (95 percent confidence interval, 25 to 72 percent) in 252 breasts radiated prior to reconstruction versus 39 percent (95 percent confidence interval, 24 to 55 percent) in 708 breasts exposed to radiation after reconstruction.

Failure of Reconstruction/Need for Flap

Nineteen studies (7,8,10,11–15,18,20–23,25–29,32) reported data on failed attempts at implant based reconstruction and the need for flaps in addition to or as replacements of previously placed implants with values ranging from 2 to 45 percent (25, 22). The pooled rate of implant reconstruction failure and need for flaps was 19 percent (95 percent confidence interval 10 to 29 percent) in 377 breasts exposed to pre-reconstruction radiation versus 20 percent (95 percent confidence interval 15 to 25 percent) in 977 breasts exposed to radiation after reconstruction. The forest plot shown in Figure 2 depicts the variability in failure rates among studies; however, the pooled estimate and confidence intervals are similar for failure rates regardless of the timing of radiation therapy to reconstruction.

Completion of Implant Based Reconstruction

Eight studies (7,8,12–14,25,26,32) reported data on the number of reconstructions that were successfully completed with implants as was initially intended with values ranging from 59 to 97 percent (7, 25). The pooled rate of successful implant reconstruction was 83 percent (95 percent confidence interval 68 to 94 percent) in 311 breast exposed to pre-reconstruction radiation versus 80 percent (95 percent confidence interval 68 to 90 percent) in 321 breasts with post-reconstruction radiation.

DISCUSSION

The utilization of implant reconstruction in mastectomy patients appears to be on the rise. A recent study by Albornoz et al (33), querying the Nationwide Inpatient Sample from 1998 to 2008, reported an average increase of 11% per year of immediate implant-based reconstruction, with a widening gap of this technique relative to autologous forms of reconstruction over time. Possible reasons suggested for this increase include a growing population of younger patients who require mastectomies and lack sufficient adiposity for autologous reconstruction, in addition to a possible cultural shift in breast aesthetics with a preference for a non-ptotic appearing breast. Another reason is a possible increasing acceptance of silicone implants since its re-approval by the FDA for general use in 2006. Unfortunately, the registry did not permit an assessment of implant reconstruction rates in the setting of radiation therapy or in a delayed fashion.

The more thorough studies investigating the effect of the relative time of exposure to radiation therapy on outcomes of implant reconstruction were included in this review in an attempt to get a better grasp of the impact of radiation timing on implant based breast reconstruction. In 2012, Spear and colleagues (8) looked at postoperative outcomes in two-stage implant reconstructions with use of Alloderm (Lifecell, Branchburg, NJ) in 73 patients exposed to radiation therapy prior to or after beginning the reconstruction process. Post-reconstruction radiated patients were found to have higher rates of reconstruction failure (21.4% vs 11.8%) and a need for flaps in addition to the implant or as a replacement (16.1% vs 5.9%) when compared to pre-reconstruction radiated patients. Even higher rates of reconstruction failure in pre-reconstruction radiated patients, were reported by Hirsch et al. (7). In their retrospective review of outcomes in patients exposed to pre-reconstruction radiation therapy, major complications requiring implant removal or conversion to flaps

occurred in as many as 39% of patients. Though most would agree that failure rates with implant reconstruction in the setting of any form of radiation therapy are higher compared to reconstruction without radiation, there is a significant discrepancy in the actual rates of complications reported even in more recent studies. A few possible explanations for these discrepancies include surgical technique differences from institution to institution, differences in the delivery of radiation therapy and the limited subset of patients undergoing radiation therapy in one form or another as part of their oncologic treatment.

Complications in this review were categorized as minor or major based on whether or not the specific complication resulted in surgical interventions or failure of reconstruction. Complications were grouped as such to give better understanding of the significance of the types of complications encountered with implant reconstruction of the radiated breast. The need to return to the operating room typically represents a complication of severity that could potentially lead to a failed reconstruction. No significant differences were found in major and minor complications between the study groups, with some overlap of confidence intervals of pooled estimates (Table 3). Pooled major complications in patients exposed to pre-reconstruction radiation was 49% (CI 0.25–0.72) and 39% (CI 0.24–0.55) in patients exposed to radiation after reconstruction. A possible explanation for this observation in major complication rates may be attributed to the fact that pre-reconstruction radiation patients are exposed to a greater number of operations following radiation with greater risk for additional injury to already compromised skin. With post reconstruction radiation, the skin is allowed some time to recover from the initial insults of a mastectomy and implant placement prior to undergoing radiation.

Capsular contractures are one of the more common complications encountered with implant reconstruction and higher grades are a primary reason for additional operations in the long-term. The true etiology of capsular contracture is unclear but it is ubiquitous to all forms of mammary implant use. Radiation therapy however, has been shown to result in higher rates of capsular contracture in implant based breast reconstruction (24,29). An independent evaluation of capsular contracture was performed given its common occurrence and potential impact on the overall outcome of reconstruction. Here also not all contractures are clinically significant as most surgeons would not operate on low grade (mild) contractures. Pooled mild and severe capsular contracture rates were not significantly different in patients exposed to post-reconstruction radiation therapy relative to patients radiated prior to beginning reconstruction. Though differences between the groups were not significant, the pooled rates of contractures in both study groups (25% and 32%) indicate that even in the absence of other complications, one in three to four patients may have a contracture severe enough to warrant an operation. This information would be helpful to patients who might be considering implant reconstruction when radiation is anticipated.

The ultimate success rates of implant reconstruction in the setting of radiation therapy delivered prior to or after reconstruction is important because it provides additional information on the feasibility of this reconstructive option. Pooled data from our analysis showed similar rates of reconstruction failure or the need for flaps in patients exposed to radiation prior to (19 %) or after the initiation of breast reconstruction (20 %). Reconstruction completion rates for pre-reconstruction and post-reconstruction radiated

breasts were 83% and 80% respectively, which are in agreement with the pooled failure rates. These failure rates are lower than seen in early individual reports (30) likely reflecting changes attributable to evolving surgical techniques and changes in radiation delivery. One major change in surgical technique over the past few years is the widespread use of acellular dermal matrices (ADMs) for partial coverage of implants. Of note however, a recent single center retrospective comparison of ADM use to submuscular implant coverage in the setting of radiation found no difference in the complication rates associated with these techniques (35).

This study has a number of limitations. Most importantly, the results found are limited by the strength of the available evidence in the literature. Heterogeneity between included studies was significant likely due to clinical and methodological differences between studies. Additionally, there was an absence of randomized control trials exploring this important question. There were fewer published studies in the literature that presented data on patients exposed to pre-reconstruction radiation therapy, likely due to the fact that a good number of surgeons opt for autologous reconstruction in this setting. Outcomes reported by individual studies were also not uniform precluding rigorous statistical analysis. We were, however, able to shed light on patterns in complication rates and bring the need for prospective trials studying the role of implant reconstruction in the setting radiation therapy to the attention of physicians and researchers.

CONCLUSION

Radiation therapy, though a critical component of breast cancer therapy, is associated with higher rates of implant based reconstruction complications relative to similar reconstructive techniques in the absence of radiation (9). In this analysis to determine complication rates and potential differences in implant reconstruction outcomes as a result of variations in the time of exposure to radiation, we found similar overall success and failure rates; failure rates were clinically significant in both groups. Though technically feasible, implant based reconstruction in the setting of radiation therapy is associated with relatively high rates of complications. Patients should be counseled appropriately on these potential complications in order that they may make fully informed decisions.

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Figure 1.
Attrition diagram

Figure 2.
Forest Plot of the proportion of Failed Attempts at Implant Based Reconstruction and the need for flaps. Diamonds represent the overall summary estimate.

Table 1

Predetermined Inclusion and Exclusion Criteria for literature Search

Inclusion Criteria
Primary data from prospective and retrospective observational studies
Human Studies
Studies that include data on single or two staged implant breast reconstruction
Studies that stratify results based on delivery of radiation therapy before or after initiation of reconstruction
Exclusion Criteria
Review, technique or case report articles
Studies with fewer than 10 total patients with pre or post reconstruction radiation therapy
Studies focused solely on the elderly (older than 65years)
Studies with no relevant extractable outcomes
Studies not published in English

Table 2

Study and Patient Characteristics

Authors	Year	Study Design	Patient No.	Breast No.	Mean Age (Years)	Pre vs Post Recon XRT	Reconstructive Technique	Follow Up Months (Range)
Spear et al.	2012	Retrospective	N/A	73	46.1	Both	Two stage breast reconstruction	15.2 ** (6–80.5)
Lin et al.	2012	Retrospective	N/A	49	45.2	Both	Two stage breast reconstruction	27.2 (N/A)
Hirsch et al.	2012	Retrospective	76	81	52.3	Pre-Recon XRT	Two stage breast reconstruction	35 (N/A)
Ho et al.	2012	Retrospective	151	151	44	Post Recon XRT	Two stage breast reconstruction	86 ** (11–161)
Peled et al.	2012	Retrospective	56	N/A	N/A	Both	Two stage breast reconstruction	52.5 (41–71)
Hvilsom et al.	2012	Retrospective	125	125	N/A	Pre-Recon XRT	Single & Two stage breast reconstruction	N/A
Monrigalet al.	2011	Retrospective	22	22	N/A	Pre-Recon XRT	Not Specified	96 (12–240)
Nava et al.	2011	Retrospective	159	159	49	Post Recon XRT	Two stage breast reconstruction	50 ** (N/A)
Kronowitz et al.	2011	Retrospective	43	43	N/A	Post Recon XRT	Two stage breast reconstruction	40 ** (8–85.3)
Berry et al.	2010	Retrospective	97	105	50.8	Both	Two stage breast reconstruction	N/A
Christante et al.	2010	Retrospective	25	25	N/A	Post Recon XRT	Two stage breast reconstruction	31 ** (1–101)
Lee et al.	2010	Retrospective	N/A	13	N/A	Post Recon XRT	Two stage breast reconstruction	N/A
Cowen et al.	2010	Prospective	141	141	49.8 *	Post Recon XRT	Two stage breast reconstruction	37 (10–107)
Prothet et al.	2009	Retrospective	33	33	49	Post Recon XRT	Two stage breast reconstruction	24.9 (2.6–119.9)
Anderson et al.	2009	Retrospective	74	74	46 *	Post Recon XRT	Two stage breast reconstruction	48 (9–200)
Jhaveriet al.	2008	Retrospective	69	69	54 *	Post Recon XRT	Two stage breast reconstruction	38 (3–98)
Nahabedian et al.	2008	Retrospective	N/A	47	47	Both	Two stage breast reconstruction	26.9 (12–68)
Cordieroet al.	2006	Retrospective	91	N/A	48.1	Both	Two stage breast reconstruction	36.7 (12–103)
Anderson et al.	2004	Retrospective	50	50	45	Both	Two stage breast reconstruction	28 ** (1–153)
Cordieroet al.	2004	Retrospective	81	81	48.5	Post Recon XRT	Two stage breast reconstruction	34 (N/A)
Tallet et al.	2003	Prospective	55	55	51.5	Both	Two stage breast reconstruction	25 ** (19–42)
Contant et al.	2000	Retrospective	28	28	46	Both	Two stage breast reconstruction	30 ** (7–67)
Spear et al.	2000	Retrospective	40	40	47.9	Both	Two stage breast reconstruction	28 (11–76)
Benediktsson et al.	1999	Prospective	19	19	53	Post Recon XRT	Single stage breast reconstruction	N/A

Authors	Year	Study Design	Patient No.	Breast No.	Mean Age (Years)	Pre vs Post Recon XRT	Reconstructive Technique	Follow Up Months (Range)
Von Smitten et al.	1992	Prospective	13	13	N/A	Post Recon XRT	Two stage breast reconstruction	30 (6-44)
Barreau-Pouhaer et al.	1992	Retrospective	41	41	N/A	Both	Single stage breast reconstruction	38(N/A)

XRT- Radiation Therapy

* Median age

** Median follow-up

Table 3

Summary of Overall Estimates and 95% CI for Complication Rates

Complication Rate	Pre or Post XRT Reconstruction	Number of Studies	Number of Breasts	Weighted Point Estimate and 95% CI	Test of Heterogeneity <i>P</i> -value	I ²
Minor Complications	Pre	4	150	0.18 (0.05–0.36)	0.0036	77.9 (40.2–91.8)
	Post	4	246	0.31 (0.17–0.463)	0.0003	81 (55.8–91.9)
Major Complications	Pre	8	252	0.49 (0.25–0.72)	<0.0001	92.4 (87.4–95.4)
	Post	14	708	0.39 (0.24–0.55)	<0.0001	94.2 (91.9–95.9)
CC I & II	Pre	4	98	0.30 (0.00–0.77)	<0.0001	94.8 (89.7–97.4)
	Post	9	672	0.37 (0.20–0.55)	<0.0001	95.4 (93.1–97)
CC III & IV	Pre	3	68	0.25 (0.10–0.45)	0.0674	62.9 (0–89.4)
	Post	10	818	0.32 (0.20–0.46)	<0.0001	93.2 (89.4–95.6)
Failure/Need for flap	Pre	10	377	0.19 (0.10–0.29)	<0.0001	75.1 (53.6–86.6)
	Post	16	977	0.20 (0.15–0.25)	<0.0001	67.7 (45.7–80.8)
Completion	Pre	6	311	0.83 (0.68–0.94)	<0.0001	87.8 (75.8–93.8)
	Post	5	321	0.80 (0.68–0.90)	0.0037	74.3 (36.2–89.6)

XRT- Radiation Therapy CC- Capsular Contracture