Outcomes of Immediate Tissue Expander Breast Reconstruction Followed by Reconstruction of Choice in the Setting of Postmastectomy Radiation Therapy

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Abstract: A common sequence for performing staged tissue expander breast reconstruction is to immediately insert a tissue expander, complete expansion before radiotherapy, and then perform the definitive reconstruction after radiotherapy is complete. This study evaluates the outcomes of this treatment regimen in 237 patients over a 10-year period at Northwestern Memorial Hospital. Overall, 62% of the patients successfully completed tissue expander/ implant reconstruction, 22.3% experienced major complications leading to explantations or conversions to flap, and 13.5% completed tissue expander/ elective autologous reconstruction. Of the patients who underwent second-stage tissue expander to implant exchange, 87.5% successfully completed reconstruction without experiencing complications leading to explantation or conversion to autologous reconstruction. Thus, this study indicates that immediate tissue expander followed by reconstruction of choice breast reconstruction in the setting of postmastectomy radiation therapy can be successfully performed in most of the patients.

Key Words: breast reconstruction, tissue expander, implant, radiation

(Ann Plast Surg 2014;72: 274-278)

he negative effects of radiation therapy are well known to reconstructive surgeons. Several studies have demonstrated increased complication rates in patients who undergo implant-based¹⁻⁴ or autologous⁵ breast reconstruction in the setting of postmastectomy radiation therapy (PMRT). When PMRT is anticipated, patients and surgeons will often opt for 1 of 3 approaches: immediate microsurgical reconstruction with autologous tissue before PMRT, delayed reconstruction with an autologous reconstruction after PMRT is completed, or immediate reconstruction with a tissue expander followed by a second-stage implant exchange. This latter approach is not universally accepted by plastic surgeons because of the possibility of complications such as painful contractures, implant loss, and suboptimal cosmesis.

To optimize the outcomes of expander/implant breast reconstruction in the setting of PMRT, surgeons have proposed variations in the cancer treatment/reconstructive algorithm. Two well-described algorithms have been published: (1) performing the tissue expander implant exchange before radiation⁶ and (2) mandating that all patients who undergo PMRT progress to autologous tissue reconstruction.⁷ At Northwestern Memorial Hospital, we prefer a sequence of mastectomy, tissue expansion, radiation therapy, and then definitive reconstruction of choice. Some patients may elect to undergo implant

Conflicts of interest and sources of funding: none declared.

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DOI: 10.1097/SAP.0b013e318268a7ea

reconstruction, whereas others may undergo autologous reconstruction. We feel that this approach allows us to avoid delays in beginning radiation therapy and to maximize reconstructive options.⁸ This study evaluates the outcomes of this treatment regimen.

METHODS

The charts of a consecutive series of 242 patients who underwent tissue expander/reconstruction of choice breast reconstruction in the setting of PMRT at Northwestern Memorial Hospital between July 1, 1998, and August 20, 2008, were retrospectively reviewed. Only patients who underwent immediate tissue expander insertion after mastectomy were included in this analysis. Patients who underwent immediate autologous reconstruction were excluded. In addition, the charts of 5 patients were incomplete and were excluded from analysis. Mastectomies were performed by 11 attending general surgeons, and reconstructive procedures were performed by 6 attending plastic surgeons.

Approach to Reconstruction

The rationale for the reconstructive sequence used in this study was described by the authors in a prior publication.⁸ In general, the tissue expanders were inserted immediately after mastectomy. The decision process regarding the use of whether to use acellular dermal matrices was also described in a separate study.9 Expansion began approximately 10 to 14 days after surgery or when deemed appropriate by the attending surgeon and was carried out until the desired volume was achieved, which was a volume that provides a rounded breast form but does not protrude excessively or interfere with radiation planning. Once this was complete, the patient underwent radiation therapy. After sufficient time elapsed so that the tissues were healed, radiation therapy was complete, and the effects of radiation were apparent (typically 3-6 months), a decision was made to proceed with either autologous reconstruction or exchange for a permanent implant. During this decision-making process, it was critical to include input from both the patient and the surgeon. In general, as long as the appearance and character of the breast tissue were deemed acceptable by the surgeon, patients could elect to pursue either autologous or implant-based reconstruction. However, in certain situations such as in patients who demonstrated severe sequelae of radiation therapy (significant erythema and fibrosis), exchange for a permanent implant was not deemed to be an appropriate option by the surgeon. These patients were either observed for improvement or were offered autologous reconstruction. Other factors that placed the patient at heightened risk for complications such as increased body mass index (BMI) and active smoking were taken into account. In summary, the choice of definitive reconstruction was made by balancing patient desires with what was deemed safest and most appropriate by the surgeon.

Data Analysis

In this study, only the outcomes of radiated breasts were analyzed. For example, if the patient had a bilateral procedure and only

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Annals of Plastic Surgery • Volume 72, Number 3, March 2014

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Major Complications Requiring Major Complications Requiring Minor Complications Surgical Correction Explantation or Conversion to Flap Minor wound healing abnormalities Radiation-induced mastectomy flap necrosis Major wound healing abnormalities Minor mastectomy flap necrosis treated conservatively Major mastectomy flap necrosis Threatened implant exposure treated by excision and closure Infection treated by intravenous antibiotics alone Threatened exposure Implant exposure Pain/tightness Seroma treated by percutaneous drainage Implant exposure Infection Pain/tightness limiting expansion Pain/tightness Poor cosmesis Injection port migration Implant deflation Hematoma

TABLE 1. Distribution of Complications

1 side was radiated, then only the radiated side was included in this analysis. Because patients underwent radiation therapy at multiple centers, limited information regarding this therapy was available to the investigators, so it was not possible to include data regarding timing and dosing of radiation in this study. Demographic factors, surgical and oncological factors, and specific information about complications were recorded. Complications were evaluated by end outcome: minor complications treated conservatively, major complications requiring surgical intervention, and major complications requiring explant/ conversion to flap. The distribution of complications is demonstrated in Table 1.

Complaints of pain/tightness and poor cosmesis were only included as complications if they required surgical revision after the definitive implant exchange. Erythema or infection treated with oral antibiotics only was not included as a complication. Multiple linear regression analysis was used to determine statistical significance of the results.

RESULTS

The mean patient age in this study was 47 years (range, 21-79 years). The mean BMI was 25.8 kg/m^2 (range, $16.8-57.6 \text{ kg/m}^2$). A total of 28 patients reported smoking in the past month. The mean follow- up time was 33 months. Acellular human dermis was used in 51 patients to provide coverage of the tissue expander during the first stage, whereas a serratus muscle or serratus fascia flap was used for the same purpose in 187 patients. Based on the pathology specimens, 8.6% of the patients had stage 1 disease, 60.8% had stage 2 disease, and 30.6% had stage 3 disease. The mean tumor size was 3.95 cm. Of the patients, 71.2% underwent axillary dissection at the time of their initial procedure. Of these patients, the mean number of lymph nodes excised was 15.2, with a mean of 5.8 positive nodes found per patient. In addition, approximately 50% of patients underwent radiation therapy at Northwestern Memorial Hospital, where the standard dose is 50 to 60 Gy, delivered over 25 to 30 doses. The remainder of the patients underwent radiation therapy at other centers, and their information was not available for inclusion in this study.

As discussed previously, the charts of 242 patients were retrospectively reviewed, and 5 were incomplete and were excluded from analysis. Thus, the charts of 237 patients were included in this study. In this first stage of reconstruction, a number of complications/ explantations occurred before breast radiation. These are shown in Table 2.

Complications and explantations during the tissue expander insertion stage of the procedure that occurred after breast radiation and before the tissue expander to implant exchange are demonstrated in Table 3.

Total complications for the first stage of reconstruction, including both complications that occurred before and after breast radiation, are shown in Table 4.

In the first stage of reconstruction, 33 patients experienced complications that led to explant or conversion to flap, 3 had adjustable implants (rather than tissue expanders) placed and did not require any additional procedures, 4 were explanted to facilitate further treatment, 3 died, and 3 chose not to pursue further reconstruction. In addition, 32 patients electively converted to autologous reconstruction because of either a previously stated desire for autologous reconstruction or dissatisfaction with the expander, which was most commonly expressed as pain/tightness or poor cosmesis. This option was discussed with the patients before surgery according to the reconstructive algorithm described by the authors.⁸ Thus, the conversions to autologous reconstructions were not considered to be complications in these 32 patients. Consequently, 159 patients underwent tissue expander to implant exchange. The results of the second stage of reconstruction are displayed in Table 5.

Using multiple linear regression analysis, smoking within the past month had no statistically significant effect on overall complication rates or on the explant or conversion to flap rate. In addition, there was no statistically significant difference in complication rates between the group in which acellular dermis was used as compared with the groups in which a serratus muscle or serratus fascia flap was used to provide coverage of the tissue expander/implant during the tissue expander insertion stage (P > 0.05 in all cases). The specific

TABLE 2. Complications of Tissue Expander Stage That Occurred Before Radiation Therapy							
Complications Before Radiation	No. Patients	No. Breasts	Minor Complications	Major Requiring Surgical Intervention	Major Requiring Explant or Flap	Total	
Tissue expander insertion stage, n	237	240	18	22	14	54 (in 50 patients)	
Percent per patient			8	9	6	23	

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TABLE 3. Complications of the Tissue Expander Stage That Occurred After Breast Radiation and Before the Tissue Expander to Implant Exchange

Complications After Radiation	No. Patients	No. Breasts	Minor Complication	Major Requiring Surgical Intervention	Major Requiring Explant or Flap	Total
Tissue expander insertion stage, n	221	224	0	4	19	23 (in 22 patients)
Percent per patient			0	2	81	10

Of the 237 patients who underwent the initial tissue expander insertion, 14 patients experienced complications that led to explantation before radiotherapy, and 2 patients were explanted to facilitate further treatment before receiving radiotherapy. Thus, 221 patients underwent radiotherapy with a tissue expander in place.

Total Complications	No. Patients	No. Breasts	Minor Complications	Major Requiring Surgical Intervention	Explant or Conversion or Flap	Total
Tissue expander insertion stage, n	237	240	19	26	33	78 (in 73 patients)
Percent per patient			8	11	14	33

plastic surgeon or oncological surgeon did not affect total complication rate or explant/conversion to flap rate. Axillary dissection during the initial procedure also did not affect total complication rate or the explant/conversion to flap rate. However, increased BMI and increased age were found to be statistically significant independent risk factors for both increased complication rates and increased explant or conversion to flap rates (P < 0.05).

A closer evaluation of the causes for explantation or conversion to flap is shown in Table 6.

In summary, 62% of the patients completed tissue expander/ implant reconstruction, 22.3% experienced major complications leading to explantations or conversions to flap, 13.5% completed tissue expander/elective autologous reconstruction, and 2.2% experienced other outcomes as described previously.

DISCUSSION

Although the current literature widely varies with regard to what constitutes a complication, several studies report that the use of PMRT increases the overall complication rates in implant-based breast reconstruction to as high as 68%, ^{1-4,10-12} with a long-term "failure" or implant loss rate of approximately 20% to $50\%^{10,13}$. Because of methodological differences, it is difficult to closely compare the results of this study to previous studies because of differing criteria

for complications and lack of information about the timing of complications with respect to stage of the procedure. With the reconstructive sequence described in this study, approximately 62% of the patients completed tissue expander/implant reconstruction, and 13.5% completed tissue expander/autologous reconstruction, with an overall rate of explantation or conversion to flap of 22.3%. This is the largest series to date that evaluates the outcomes of this type of reconstruction in the setting of PMRT. As mentioned previously, it is difficult to compare the results of this study to the results of previous studies because of methodological differences, but based on these results, the outcomes of this study are grossly consistent with other tissue expander breast reconstruction algorithms previously published in the literature.

The central question addressed by this study is to determine if implant-based reconstruction in the setting of PMRT is a viable reconstructive option, with an acceptable complication profile. To fully evaluate this question, it is important to understand that, with all immediate tissue expander breast reconstructions, there is a risk of perioperative complications that exists independent of future radiation therapy. As demonstrated by Figure 1, a significant number of complications leading to explantation or conversion to flap occurred early in the perioperative period.

As shown in Figure 1, patients in the tissue expander stage experienced a 14% major complication requiring explanation or

TABLE 5. Total Complications After the Permanent Implant Has Been Placed							
Total Complications	No. Patients	No. Breasts	Minor Complication	Major Requiring Surgical Intervention	Explant or Conversion to Flap	Total	
Permanent implant, n	159	162	1	25	20	46 (in 38 patients)	
Percent per patient			<1	15.6	12.5	28.8	

Reasons for Explant or Conversion to Flap	Infection	Pain/ Tightness	Poor Cosmesis	Exposure	Threatened Exposure	Radiation Burn Leading to Skin Necrosis
Tissue expander insertion, n	19 (11 before XRT, 8 after)	4	0	6 (2 before XRT, 4 after)	3 (2 before XRT, 1 after)	1
Tissue expander to implant exchange, n	7	5	1	7	0	0
Total, n	26	9	1	13	3	1

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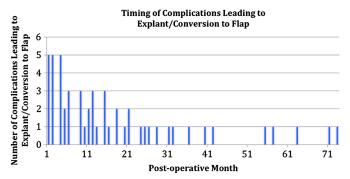


FIGURE 1. Timing of complications leading to explantation or conversion to flap.



FIGURE 2. Patient who underwent immediate tissue expander placement followed by exchange to a permanent implant. From left to right, preoperative, tissue expander stage, and definitive implant stage.

conversion to flap rate (6% before radiation, 8% after radiation), and patients in the second-stage experienced a 12.5% explant or conversion to flap rate. Thus, 6% of complications leading to explantation or conversion to flap during the first reconstructive stage would have occurred regardless of the radiation therapy. Moreover, the complication leading to explantation/conversion or conversion to flap rate in women who undergo tissue expander to implant exchange is 12.5%. Therefore, in women who successfully complete the tissue expander stage and undergo conversion to a permanent implant, there is an 87.5% chance of keeping the final implant, indicating that PMRT should not be considered an absolute contraindication for implant-based reconstruction (Figs. 2, 3).

In this study, it was observed that approximately 13.5% of patients in the first stage of reconstruction elected to undergo conversion to autologous reconstruction. These patients did not experience complications that led to explantation but were either dissatisfied with their tissue expanders or had previously stated that they desired autologous reconstruction. The ability of the patient and surgeon to choose between a definitive autologous reconstruction and a definitive implant-based reconstruction is central to this treatment

algorithm. Patients need to understand that the tissue expander stage of reconstruction is temporary and is a placeholder for definitive reconstruction. If the reaction to radiation is mild, it may permit the patient to continue with implant reconstruction. However, if the reaction to radiation is severe, the patient may not be eligible to continue with implant reconstruction. In these situations, the elective change in reconstructive plan should not be considered as a "complication" or a "reconstructive failure," but rather as a different and more fully informed pathway to the end result of a successful reconstruction.⁸

When considering the timing of the tissue expander to implant exchange, some authors suggest that it may be optimal to perform this stage of the procedure before radiotherapy.⁶ However, this approach may potentially delay the start of radiation therapy and may also require additional procedures to correct postradiation asymmetries that could have otherwise been corrected during the tissue expander to implant exchange. Thus, to optimize results and minimize the number of additional procedures, the authors believe that the tissue expander to implant exchange is best performed after PMRT is complete. To guide patients through this stage of the procedure, effective communication with the patient is essential. Patients should be reassured



FIGURE 3. Patient who underwent immediate tissue expander placement followed by elective conversion to autologous reconstruction. From left to right, preoperative, tissue expander stage, and autologous reconstruction stage.

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that pain/tightness is typically worst during the tissue expander portion of the reconstruction, and if it does not improve after a permanent implant has been placed and other corrective measures have been taken or if they cannot tolerate the discomfort, patients should be further assured that other autologous reconstructive options are available.

Plastic surgeons in clinical practice generally do not have control of radiation dosimetry or timing, and treatment decisions are generally based on the clinical presentation of the patient rather than on the radiation dosimetry. This study is not designed to evaluate the effects of specific protocol of radiation dosimetry on the outcomes of tissue expander/reconstruction of choice breast reconstruction. Rather, this study provides information as to the outcomes of this reconstructive algorithm when applied to all patients who have undergone PMRT, regardless of their individual doses. Another limitation of this study is a lack of information regarding aesthetic evaluation and patient satisfaction. Although not a main focus of this study, this information would be useful for patients and physicians alike and should be evaluated in future, prospective studies.

CONCLUSIONS

This study demonstrates that immediate tissue expander followed by definitive breast reconstruction of choice in the setting of PMRT is a viable treatment algorithm and that PMRT should not be an absolute contraindication for implant-based reconstruction. The challenge for surgeons is to determine which patients are acceptable candidates for implant-based reconstruction and which would have an unacceptable risk of complications. With this in mind, in a separate publication,¹³ the authors have proposed a modified classification system for capsular contracture. In addition to aiding future research, this system may help guide surgeons and patients when faced with difficult treatment decisions by delineating subgroups of radiated patients who may benefit from different therapies. When this system and the methods described in this study are used, patients should be reassured that they can safely complete their cancer therapy while still being able to subsequently achieve an acceptable reconstruction with implants alone approximately 62% of the time and with the addition of autologous tissue approximately 13.5% of the time.

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