Do We Need Support in Prepectoral Breast Reconstruction? Comparing Outcomes with and without ADM

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Background: The majority of two-stage prepectoral breast reconstruction has been described utilizing acellular dermal matrix (ADM). Although reports of prepectoral breast reconstruction without ADM exist, there is a paucity of comparative studies.

Methods: A single-institution retrospective review was performed of consecutive patients undergoing immediate prepectoral two-stage breast reconstruction with tissue expanders from 2017 to 2019. Short-term reconstructive and aesthetic complications were compared between cases that utilized ADM for support and those that did not.

Results: In total, 76 cases (51 patients) were identified, of which 35 cases utilized ADM and 41 did not. Risk factors and demographics were similar between the two cohorts with the exception of body mass index, which was higher in the ADM cohort (29.3 versus 25.4, \(P = 0.011\)). Average follow-up length was also longer in patients who received ADM (20.3 versus 12.3 months, \(P < 0.001\)). Intraoperative expander fill was higher in patients who did not receive ADM (296.8 cm\(^3\) versus 151.4 cm\(^3\), \(P < 0.001\)) though final implant size was comparable in both cohorts (\(P = 0.584\)). There was no significant difference in the rate of any complication between the ADM and no ADM cohorts (25.7% versus 17.1%, respectively \(P = 0.357\)), including major mastectomy flap necrosis (\(P = 0.245\)), major infection (\(P = 1.000\)), expander explantation (\(P = 1.000\)), capsular contracture (\(P = 1.000\)), implant dystopia (\(P = 1.000\)), and rippling (\(P = 0.362\)).

Conclusions: Immediate two-stage prepectoral breast reconstruction with tissue expanders has comparable rates of short-term complications with or without ADM support. Safety of prepectoral expander placement without ADM may warrant more selective ADM use in these cases. (Plast Reconstr Surg Glob Open 2021;9:e3745; doi: 10.1097/GOX.0000000000003745; Published online 10 August 2021.)

INTRODUCTION

Prepectoral breast reconstruction has become increasingly described in the literature over the last several years. This represents a near full-circle journey from prosthesis placement in the “subcutaneous” plane,\(^1,2\) to total submuscular coverage,\(^2\) dual-plane approaches,\(^3,4\) and now muscle-sparing techniques.\(^5,6\) Critical differences in today’s procedures include refined mastectomy techniques to minimize any residual breast tissue while preserving the subcutaneous tissue and superficial perfusion,\(^7\) as well as newer-generation prosthetic devices and adjunctive tools such as acellular dermal matrix (ADM).\(^8\)

Many different technical variations of prepectoral prosthesis placement exist. However, the overwhelming majority of studies in the literature utilize ADM in some form.\(^3,6,9-12\) Described benefits of ADM use include support of the prosthetic device and pocket definition,\(^13\) decreased rippling,\(^14\) a reduced inflammatory response\(^15,16\) that may minimize capsular contracture rates, and potential protection against the deleterious effects of radiation.\(^17,18\)

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However, studies have also described immediate two-stage prepectoral reconstruction without any ADM with low short- and long-term complication rates.19,20 ADM is additionally associated with a significant cost21 and potential complications such as seroma and infection.22,23 Furthermore, with the advent of tabbed tissue expanders, that allow for fixation of the prosthesis in place, the role of ADM in two-stage prepectoral breast reconstruction has become less clear cut. However, there remains a paucity of data comparing prepectoral techniques without ADM to those with the more standardized anterior ADM support.24

The purpose of this study was to directly compare short-term outcomes in immediate tissue-expander prepectoral breast reconstruction cases with and without ADM. Analysis focused on reconstructive and aesthetic complications to better understand the safety of reconstruction without ADM and further define the role of adjunctive support materials in two-stage prepectoral breast reconstruction.

METHODS

Data Collection and Analysis

A retrospective review was performed of all patients who underwent prepectoral breast reconstruction at a single institution from 2017 to 2019 after institutional review board approval. All consecutive cases of two-stage reconstruction with immediate tissue expander placement were included for analysis. Cases utilizing a dermal flap were excluded from analysis. Cases were divided into “ADM” and “no ADM” cohorts based on if any ADM was utilized at the initial reconstruction, and variables and outcomes were compared between the two cohorts.

Patient demographics, oncologic characteristics, and mastectomy and reconstructive details were analyzed. Specifically, expander type, ADM characteristics, initial expander fill, and implant details were examined. Outcomes included reconstructive complications such as ischemic complications, infection, seroma, and reconstruction failure. Major and minor ischemic complications and infection were defined as previously described.25 Aesthetic complications including capsular contracture, implant dystopia and rippling were evaluated in patients who underwent successful implant exchange.

Surgical Indications and Technique

Ideal candidates for prepectoral reconstruction are determined preoperatively in conjunction with the breast surgeon and patient, as previously described.26 The same five breast and four plastic surgeons were involved throughout the study period with no significant changes in mastectomy or reconstruction techniques other than the variable use of ADM and type of tissue expander. ADM utilization was based on plastic surgeon preference with no specific indication or contraindication for ADM. Prosthesis placement without ADM support began in January 2019 with the availability of tabbed tissue expanders at our institution. Currently only smooth, tabbed expanders are utilized by all surgeons.

After mastectomy completion, mastectomy flap thickness27,28 and quality29 are meticulously evaluated to determine appropriateness for prepectoral prosthesis placement based on clinical examination.30 Indocyanine green angiography is not utilized given the judicious infiltration of a dilute epinephrine-containing solution. Any concern for mastectomy flap viability prompted implant placement in the subpectoral position or reconstruction delay. Intraoperative mastectomy flap evaluation did not influence ADM use if prepectoral reconstruction was deemed appropriate.

In cases with ADM, either thin medium contour perforated Alloderm (LifeCell Corp., Branchburg, N.J.) or pliable shaped perforated Flex HD (Musculoskeletal Transplant Foundation Biologics, Edison, N.J.) was utilized. ADM fixation techniques included an anterior wrap with fixation of ADM tabs to the chest wall or anterior chest wall fixation of ADM sheets (Fig. 1) with reinforcement of the inframammary fold (IMF) and anterior axillary line. ADM type, number of sheets, and ADM fixation technique was based on surgeon preference.

In cases without ADM, the mastectomy pocket is meticulously defined to achieve a conforming fit with the prosthesis and minimize the possibility of expander movement. The IMF is reinforced to the chest wall with long-lasting absorbable sutures. The lateral skin and soft tissue is then sutured to the chest wall to delineate the anterior axillary line, obliterate lateral deadspace, and ensure a snug fit with the prosthesis. (See Video [online], which displays the surgical technique for prepectoral breast reconstruction with immediate tissue-expander placement without ADM.) Tabbed tissue expanders were secured to the chest wall in the appropriate position using long-lasting absorbable sutures.

In all cases, tissue expanders were filled with saline at time of initial reconstruction based on surgeon preference and quality of the mastectomy flaps. Drains were maintained until output was more than 30 cm³/day for 2 consecutive days. Inflation typically began at 2 weeks postoperatively until the desired fill was achieved. At the time

Fig. 1. Prepectoral tissue expander in situ with two pieces of fenestrated ADM utilized to define the pocket and support the prosthesis.
of implant exchange, near circumferential capsulotomy was carefully performed with additional radial scoring to expand the implant pocket as needed. Smooth, round implants were utilized in all cases.

Statistical Analysis
A power analysis was performed to estimate the needed sample size. A moderate effect size of $w = 0.5$ was chosen to represent the predicted difference of any complication between the two groups. Given this, it was found that with an alpha of 0.05 and a power (1-beta) of 0.90, the projected sample size required was 43 cases.

Descriptive statistics and measures of central tendency were used to describe absolute and mean results, respectively. Continuous variables were first tested for normality using the Shapiro-Wilks test. Given the non-normal distribution observed, continuous and ordinal variables were compared using the Mann-Whitney U test. Categorical variables were compared using the chi-Square or Fischer exact test as appropriate. For all analyses, the level of statistical significance was set at an alpha of 0.05. All statistical analyses were performed using SPSS Statistics, Premium v25 (IBM, Armonk, N.Y.).

RESULTS
In total, 76 cases were identified (51 patients), of which 35 cases utilized ADM (Fig. 2) and 41 did not (Fig. 3). There were no significant differences in age, comorbidities, tobacco use, neoadjuvant/adjuvant therapies, and oncologic characteristics between the two groups (Table 1). An estimated 5.7% of patients in the ADM group and 14.6% in the no ADM cohort had prior radiation ($P = 0.275$), and 25.7% versus 22.0% had adjuvant radiation, respectively ($P = 0.701$). Body mass index (BMI) was higher in the ADM cohort than in the no ADM cohort (29.3 versus 25.4, $P = 0.011$). Average follow-up length was also longer in patients who received ADM (20.3 versus 12.3 months, $P < 0.001$).

The majority of mastectomies were performed for therapeutic indications in both cohorts (Table 2), though more nipple-sparing mastectomies were performed in the no ADM cohort ($P = 0.008$). Average mastectomy weight was significantly higher in the ADM cohort than in the no ADM cohort (661.8 g versus 450.8 g, $P = 0.024$).

The majority of tissue expanders were textured in both ADM and no ADM cases (74.3% and 65.9%, respectively), though tabbed tissue expanders were more frequently utilized in the no ADM cohort (87.8% versus 34.3%, $P < 0.001$) (Table 3). In cases that used ADM, most required two sheets (71.4%) of Alloderm (88.6%) using an anterior chest wall fixation technique (85.7%) rather than a wrap (14.3%). Initial intraoperative tissue expander fill was higher in patients who did not receive ADM (296.8 cm$^3$ versus 151.4 cm$^3$, $P < 0.001$). Implant size was comparable in both cohorts ($P = 0.584$), though cases without ADM were more likely to receive highly cohesive implants (72.0% versus 42.1%, $P = 0.046$).

There were no significant differences in the rate of any complication between the ADM and no ADM cohorts ($P = 0.357$) (Table 4). Rates of major ischemic complications were low in both cohorts. The ADM cohort had a major infection rate of 8.6% and seroma incidence of 2.9% (no ADM: 2.4% [$P = 0.329$] and 7.3% [$P = 0.620$], respectively). Four cases in each cohort (ADM 11.4%, no ADM 9.8% [$P = 1.000$]) required explantation of the initial tissue expander due to major mastectomy flap necrosis (25%), major infection (50%), or a combination of seroma and infection (25%). Aesthetic complications were analyzed in 44 cases after implant exchange. Grade III/IV capsular contracture rates were low in both the ADM and no ADM cohorts (0% versus 4.0%, respectively [$P = 1.000$]). Implant dystopia was present in 11.8% of

Fig. 2. Prepectoral breast reconstruction with ADM. A 60-year-old woman with a history of right breast segmental excisions and left breast cancer (A-C) who underwent bilateral skin-sparing mastectomy and immediate prepectoral reconstruction with 250ml tissue expanders and anterior ADM. The patient underwent subsequent implant exchange with smooth, round highly cohesive 310ml silicone implants (D-F).
ADM cases and 8.0% of no ADM cases ($P = 1.000$) after implant exchange. Sixteen percent of cases in the no ADM cohort had notable rippling compared with 5.0% in the ADM cohort ($P = 0.357$).

**DISCUSSION**

ADM is one of the many tools of the plastic surgeon and has been a mainstay in the prepectoral breast reconstruction literature. However, as with all other procedures in plastic surgery, treatment must be individualized to each patient to obtain the optimal results. There is no “one approach for all.” Hidalgo et al recently published a more selective and successful algorithm for using ADM in the treatment of capsular contracture. Similarly, more selective use of ADM may be possible in two-stage tissue expander breast reconstruction, as evidence has shown the possibility of successful prepectoral breast reconstruction with low complication rates without ADM.

After the availability of tabbed tissue expanders at our institution in early 2019, the use of ADM decreased significantly (96.1% cases before this date and 20.0% after this date used ADM). The logic behind this transition was that fixation of the tissue expander in place addresses prosthesis support while tailoring of the mastectomy flaps allows for pocket definition. However, concern over a change in overall complications based on certain issues that may be mitigated by ADM such as pressure ischemia of the mastectomy flap, implant dystopia, and capsular contracture was the impetus for this study.

Our results demonstrated a low and comparable rate of complications between the ADM and no ADM cohorts. Importantly, there was no significant difference in major or minor mastectomy flap necrosis in cases without ADM. The most significant potential concern in an “unsupported” expander would be the weight of the tissue expander, particularly with saline fill, on mastectomy flaps that could compromise perfusion. Intraoperative expander fill was actually higher in the no ADM cohort, possibly secondary to increased comfort with the procedure later in the study period, though no differences in

**Table 1. Patient Demographics and Oncologic Characteristics in Two-Stage Prepectoral Reconstruction Cases with and without ADM**

|                          | Total          | ADM            | No ADM         | P   |
|--------------------------|----------------|----------------|----------------|-----|
| Breasts                   | 76             | 35             | 41             | —   |
| Patients                  | 51             | 23             | 28             | —   |
| Age (y)                  | 52.1 ± 1.2     | 51.4 ± 1.7     | 52.6 ± 1.7     | 0.735 |
| Mean BMI (kg/m²)          | 27.2 ± 0.8     | 29.3 ± 1.2     | 25.4 ± 0.9     | 0.011 |
| Diabetes mellitus         | 6 (7.9%)       | 3 (8.6%)       | 3 (7.3%)       | 1.000 |
| Active tobacco use        | 1 (1.3%)       | 0              | 1 (2.4%)       | 1.000 |
| Former tobacco use        | 22 (28.9%)     | 9 (25.7%)      | 13 (31.7%)     | 0.566 |
| Prior breast augmentation | 3 (3.9%)       | 0              | 3 (7.3%)       | 0.245 |
| Prior breast reduction    | 6 (7.9%)       | 5 (14.3%)      | 1 (2.4%)       | 0.089 |
| Prior lumpectomy          | 16 (21.1%)     | 7 (20.0%)      | 9 (22.0%)      | 0.835 |
| Previous radiation        | 8 (10.5%)      | 2 (5.7%)       | 6 (14.6%)      | 0.275 |
| Previous chemotherapy     | 21 (27.6%)     | 7 (20.0%)      | 14 (34.1%)     | 0.169 |
| Postoperative radiation   | 18 (23.7%)     | 9 (25.7%)      | 9 (22.0%)      | 0.701 |
| Postoperative chemotherapy| 25 (32.9%)     | 13 (37.1%)     | 12 (29.3%)     | 0.466 |
| Cancer stage              |                |                |                | 0.202 |
| k 0                      | 15 (20.3%)     | 4 (12.1%)      | 11 (26.8%)     |     |
| ⅠA/IB                    | 25 (33.8%)     | 13 (39.4%)     | 12 (29.3%)     |     |
| ⅡA/ⅡB                   | 21 (28.4%)     | 8 (24.2%)      | 13 (31.7%)     |     |
| ⅡIA/ⅡIB/ⅡIC             | 12 (16.2%)     | 7 (21.2%)      | 5 (12.2%)      |     |
| IV                       | 1 (1.4%)       | 1 (3.0%)       | 0              |     |
| Follow-up length (mo)†    | 16.0 ± 0.9     | 20.3 ± 1.3     | 12.3 ± 0.8     | 0.000 |
| Follow-up length since exchange (mo)† | 11.1 ± 1.1 | 14.8 ± 1.8 | 8.6 ± 1.2 | 0.008 |

†Mean ± standard error of the mean. Bold values are statistically significant.
any type of ischemic complications were noted. In a prior critical study, Manrique et al. compared two-stage prepectoral reconstructions with and without ADM in a single-surgeon retrospective study, and similarly found low and comparable rates of ischemic and other complications. Of note, the authors intraoperatively filled expanders with air, and median intraoperative expansion volume was significantly less in cases without ADM.

The argument for ADM use as prosthesis support is important in immediate implant reconstruction, but may be less relevant with the current generation of tissue expanders. Tabbed tissue expanders allow one to secure prosthesis position, and the use of long-lasting absorbable (or permanent) sutures will minimize prosthesis movement that is more notable with expanders. Textured prosthesis itself. Poor ADM adherence is a nidus for vascularized ADM is no different than exposure of the full-thickness mastectomy flap necrosis, visualizing non-vascularized ADM is no different than exposure of the prosthesis itself. Poor ADM adherence is a nidus for complications, which has led certain authors to indicate “ADM-sparing” reconstructions in the setting of compromised mastectomy flaps. Relative mastectomy flap thickness is one quantifiable component of quality; however, adequate imaging data was not available for analysis in this study. Mastectomy flap quality, though, is thoroughly evaluated based on intraoperative clinical examination in all patients who receive prepectoral reconstruction. Cases with any concern for skin envelope viability are converted to submuscular reconstructions or delayed, and therefore do not influence the ADM selection in this study population.

Despite preservation of the subcutaneous layer, the thickness of the subcutaneous tissue is highly variable among patients (Fig. 4). We have previously found a correlation between increased flap thickness and higher BMI. In the unfortunate situation of full-thickness mastectomy flap necrosis, visualizing non-vascularized ADM is no different than exposure of the prosthesis itself. Poor ADM adherence is a nidus for complications, which has led certain authors to indicate “ADM-sparing” reconstructions in the setting of compromised mastectomy flaps. Relative mastectomy flap thickness is one quantifiable component of quality; however, adequate imaging data was not available for analysis in this study. Mastectomy flap quality, though, is thoroughly evaluated based on intraoperative clinical examination in all patients who receive prepectoral reconstruction. Cases with any concern for skin envelope viability are converted to submuscular reconstructions or delayed, and therefore do not influence the ADM selection in this study population.

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Interestingly, patients without ADM had a significantly lower BMI (and mastectomy weights) than those with ADM. This may seem paradoxical, but is likely a reflection of chronological selection for prepectoral reconstruction. Initially thick flaps were likely more frequently selected for prepectoral reconstruction, which was later expanded to thinner, but still well-perfused, flaps. Highly cohesive implants were used more frequently in the no ADM patients to minimize rippling, though lower BMI and likely thinner flaps may have contributed to the rippling rate of 16% in this cohort. Autologous fat is also an excellent means of improving soft tissue coverage, and more liberal use at the time of exchange in this cohort may have further decreased this complication. Lack of ADM may have additionally been a factor as ADM is used to treat rippling; however, rates of rippling from other prepectoral studies without ADM have been lower (0%–3.6%). Though rippling was not found to be significantly different between the two cohorts in this study, a larger sample and long-term follow-up is needed to more decisively determine the need for ADM to prevent rippling, particularly in low-BMI patients.

Capsular contracture is another important outcome given the role of ADM in minimizing the inflammation leading to fibrosis and contracture. Rates of Grade III/IV capsular contracture were low in both cohorts, but were limited by short follow-up. Sigla et al reported a similar contracture rate of 3.8%, albeit with textured implants. Other long-term studies with smooth, round implants in the prepectoral plane have demonstrated a 7.6% rate of Grade III/IV contracture, suggesting a time-dependent component, though dual-plane ADM studies have shown static contracture rates after two years. Larger and longer-term comparative studies are needed to further evaluate this outcome, particularly in the setting of more recent stringent contamination prevention measures and smooth tissue expanders.

Tissue expander removal rates were similar between ADM and no ADM cases; however, overall explantation rates were high. While mastectomy techniques have remained standardized among the same five breast surgeons throughout the study period, this trend is likely reflective of an initial learning curve for both breast and plastic surgeons using prepectoral techniques. In the last six months of the study, this rate significantly decreased with two tissue expanders requiring removal (6.7%), and has continued to decline since the study period. These findings reflect the importance of mastectomy flap quality and the lower tolerance of prepectoral prosthesis for wound complications, reinforcing the importance of a coordinated approach between the breast and plastic surgeon, high quality mastectomy flaps and meticulous postoperative surveillance.

This study has several limitations, including its retrospective nature that restricts the assessment of outcomes to data retrieved from chart review. Certain reconstruction characteristics differed between the two cohorts, including a higher percentage of NSM and greater initial fill size in the non-ADM cohorts. Greater initial expander fill in the non-ADM cohort may have been secondary to multiple variables (including less tension on the skin closure), as this cohort had a higher rate of NSM, lower BMI in an attempt to achieve a larger initial breast mound, and potential differences in mastectomy flap thickness, which were unable to be objectively analyzed retrospectively. However, despite these differences, relevant complication

Fig. 4. A, Preoperative MRI of a patient with a “thick” layer of subcutaneous tissue superficial to breast capsule (red line). B, Preoperative MRI of patient with minimal subcutaneous tissue (red line) superficial to breast capsule.
rates such as mastectomy flap necrosis were similar between the two cohorts. Sample size was also limited in post-exchange patients to analyze certain differences in complications such as rippling, which may result in a type II error in comparison of these outcomes. Additionally, there is an aspect of selection bias in ideal candidates chosen for prepectoral reconstruction. However, there was no selection for ADM use that would have affected comparison of the outcomes of interest. A chronological “learning curve” likely contributed to certain observed differences between the two groups (BMI, mastectomy weight, initial tissue expander fill), though this did not affect the comparative rate of complications. Finally, long-term outcomes are needed, particularly with regard to aesthetic analysis and patient-reported outcomes.

CONCLUSIONS

Comparative outcomes in two-stage prepectoral breast reconstruction with and without ADM demonstrated the safety of immediate prepectoral expander placement without ADM support. Although certain benefits of ADM in implant-based breast reconstruction are well-known, these data suggest that more selective use of ADM may be warranted in the appropriate patients, rather than a blanket approach to these cases. In this regard, individualizing treatment choices based on the particular patient and mastectomy defect may help optimize both reconstructive and aesthetic outcomes, while minimizing cost and avoiding potential ADM-associated complications. Long-term data and comparative objective aesthetic and patient-reported outcomes from multiple institutions are needed to further refine the indications and implications of ADM use in two-stage prepectoral breast reconstruction.

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