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Breast

The BREASTrial Stage II: ADM Breast Reconstruction Outcomes from Definitive Reconstruction to 3 Months Postoperative

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Background: The Breast Reconstruction Evaluation of Acellular Dermal Matrix as a Sling Trial is a prospective randomized trial comparing outcomes of tissue expander breast reconstruction using either AlloDerm or DermaMatrix. The trial was divided into 3 outcome stages; this study reports stage II outcomes, which are those from the time of definitive reconstruction to 3 months postoperative.

Methods: A randomized trial was conducted to compare complication rates between AlloDerm and DermaMatrix groups. The impact of matrix type, age, obesity, radiation therapy, chemotherapy, and reconstruction type on complications was analyzed with regression models.

Results: Of the 128 patients (199 breasts) who were randomly assigned into the trial, 111 patients (173 breasts) were available for analysis in stage II. There was no difference in overall rates of complications (15.4% vs 18.3%, $P = 0.8$) or implant loss (2.2% vs 3.7%, $P = 0.5$) between the AlloDerm and DermaMatrix groups, respectively. Obesity was the only significant predictor of complications on regression analysis (odds ratio, 4.31, $P = 0.007$). Matrix type, age, radiation therapy, chemotherapy, or reconstruction type had no impact on the incidence/severity of complications.

Conclusions: Acellular dermal matrix (ADM) will likely continue to have a role in breast reconstructive surgery; however, caution should be taken when using ADM because of relatively high complication rates, especially in obese patients. The particular ADM product should be selected based on individual surgeon preference, experience, and success rates. These data and forthcoming long-term outcomes from the Breast Reconstruction Evaluation of Acellular Dermal Matrix as a Sling Trial will enable surgeons to carefully weigh the risks and benefits of ADM use in breast reconstruction. *(Plast Reconstr Surg Glob Open 2017;5:e1209; doi: 10.1097/GOX.0000000000001209; Published online 25 January 2017.)*

The Breast Reconstruction Evaluation of Acellular Dermal Matrix as a Sling Trial (BREASTrial) is a prospective randomized trial comparing outcomes between AlloDerm and DermaMatrix in staged breast reconstruction. The trial was divided into 3 outcome stages for ease of analysis and reporting: stage I: from time of mastectomy/tissue expander placement to definitive reconstruction (including tissue expansion, chemotherapy, and radiation therapy), stage II: from time of removal of tissue expanders and placement of a definitive implant or autologous reconstruction to 3 months postoperative, and stage III: from 3 months postdefinitive reconstruction to 2 years postoperative. The goals of the trial were to prospectively follow the outcomes of

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breast reconstruction utilizing acellular dermal matrix (ADM); to compare complications between AlloDerm and DermaMatrix groups; and to analyze the impact of age, body mass index, smoking, radiation therapy, and chemotherapy on clinical outcomes and histological analyses. The design of the trial[1] and stage I outcomes[2] have been reported previously.

Results from stage I of the BREASTrial demonstrated a 36.2% overall complication rate with a higher tissue expander loss rate for the DermaMatrix group (11.2% vs 5% in the AlloDerm group), although this was not significant ($P = 0.11$). Other complication profiles were similar between groups. The time to full expansion was nearly twice as long in the DermaMatrix group (70 vs 42 days, $P = 0.001$). Of note, there were more smokers (9.4% vs 0%, $P = 0.01$) and more patients who received radiation therapy (50% vs 31.3%, $P = 0.03$) in the DermaMatrix group. On multivariable regression analysis of the trial data, obesity was associated with a 7-fold increased risk of poor ADM integration ($P = 0.001$) and a 22% increased time until drain removal, both which were associated with tissue expander loss ($P \leq 0.01$).[2] Chemotherapy and radiation treatment did not increase the risk of complications in stage I (expansion phase) of the trial.

The purpose of this study is to report the outcomes from stage II of the trial, which will capture the complications from the time of tissue expander removal and conversion to a permanent implant and/or autologous tissue reconstruction until 3 months postoperative. Stage III and histological outcomes are forthcoming.

METHODS

Study Design

Complete details of the study design and methods have been previously published.[1] After institutional review board approval and obtaining written informed consent, patients undergoing mastectomy and immediate tissue expander reconstruction at the University of Utah and Huntsman Cancer Institute were randomly assigned to either freeze-dried AlloDerm (Lifecell, Branchburg, N.J.) or freeze-dried DermaMatrix (Synthes, West Chester, Pa. and Musculoskeletal Transplant Foundation, Edison, N.J.) (6×16 cm, thick). Tissue expansion proceeded with outcomes reported previously.[2] Definitive reconstruction with a permanent implant and/or autologous tissue was then performed after expansion was complete no sooner than 3 months after mastectomy, 3 weeks after final chemotherapy dose, and 12 weeks after completion of radiation therapy. All patients who required radiation therapy or those with significant skin necrosis/wound healing problems during stage I were recommended to undergo autologous reconstruction. Otherwise patients proceeded with implant-based reconstruction. This trial is registered under the name "The BREASTrial: Breast Reconstruction Evaluation Using Acellular Dermal Matrix as a Sling Trial," ClinicalTrials.gov identification number NCT00872859 (http://clinicaltrials.gov/ct2/show/study/NCT00872859).

Outcome Measures

The primary outcome measure was the incidence and grade of complications in the entire cohort and in the AlloDerm and DermaMatrix groups during stage II. Secondary outcome measures included the impact of matrix type, age, obesity, radiation therapy, chemotherapy, and type of reconstruction (implant vs autologous) on complication rates. All complications were recorded and graded on a scale from 0 to 4 depending on the intervention required (0 = none, 1 = dressing changes, increased clinic visits/procedures, 2 = hospital admission, intravenous antibiotics/pain control, 3 = surgical intervention in operating room, or 4 = implant removal).

Statistical Analysis

Statistical analysis was performed by using Fisher's exact test (if $n \leq 5$) and chi-square test (if $n > 5$) for nominal variables (ie, complication yes vs no) and Mann-Whitney U tests for ordinal variables (ie, complication grade 1–4) to compare differences in complications between groups. Univariable and bivariable logistic regression was performed to assess the effect of matrix type, age, obesity, radiation therapy, chemotherapy, and type of reconstruction on complication rates. A $P < 0.05$ was considered significant.

RESULTS

Patient Enrollment and Follow-Up

Of the 128 patients (199 breasts) who were randomized in the trial, 111 patients (173 breasts) were available for analysis in stage II with similar numbers in each group (AlloDerm: 57 patients, 91 breasts; DermaMatrix: 54 patients, 82 breasts; Fig. 1). In the AlloDerm group, 2 patients (3 breasts) were lost to follow-up and 1 patient died from the disease during stage I. In the DermaMatrix group, 3 patients (6 breasts) were lost to follow-up during stage I. The majority of patients were healthy white nonsmokers. Updated stage II patient and breast level demographics are given in Table 1. Notably, there were more smokers, more patients who received chemotherapy, and more patients who received radiation therapy in the DermaMatrix group.

Reconstruction Type

Definitive reconstruction was approximately 75% implant based and 25% autologous including latissimus dorsi flaps with an implant (9.2%), deep inferior epigastric perforator flaps (8.8%), transverse rectus abdominis myocutaneous flaps (6.4%), and superficial inferior epigastric artery perforator flaps (0.6%; Table 2). There was no significant difference in the type of breast reconstruction between groups on the patient level ($P = 0.47$) or the breast level ($P = 0.09$).

Primary Outcome Measures

During stage II, the overall complication rate was 16.8% with just under half being major complications (7.5%) that required inpatient and/or operative management. Infection was the most common complication (4.6%) followed by wound separation (3.5%), skin necrosis (2.9%), and hema-

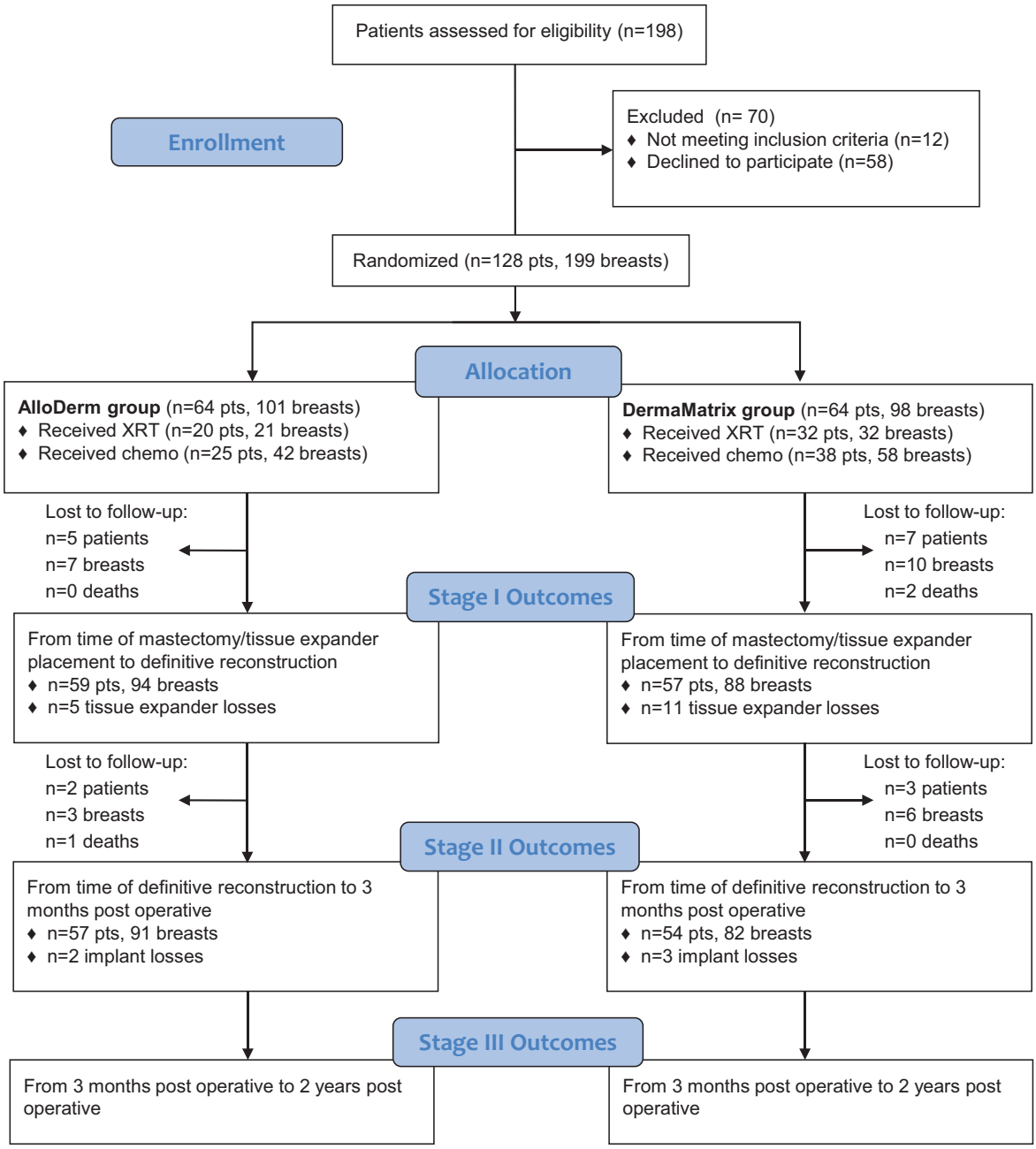

Fig. 1. BREASTrial flowchart and outcome stages. Adapted from the study by Mendenhall SD, Anderson LA, Ying J, et al. The BREASTrial: stage I. Outcomes from the time of tissue expander and acellular dermal matrix placement to definitive reconstruction. *Plast Reconstr Surg*. 2015;135:29e–42e. Used with permission from the publisher. Chemo, chemotherapy; Pts, patients; XRT, radiation therapy.

toma (0.6%). The overall implant loss rate was 2.9% during this stage of the trial. When analyzing differences between the AlloDerm and DermaMatrix groups, there was no difference in overall rates of complications (15.4% vs 18.3%, $P = 0.5$), complication grade (1.8 vs 2.5, $P = 0.2$), infection (3.3% vs 6.1%, $P = 0.3$), wound separation (4.4% vs 2.4%, $P = 0.2$), skin necrosis (2.2% vs 3.7%, $P = 0.7$), implant loss (2.2% vs 3.7%, $P = 0.5$), other (2.2 vs 2.4, $P = 0.7$), hematoma (1.1% vs 0%, $P = 0.5$), or seroma (0% vs 0%, $P =$ not applicable; Table 3). The "other" category included 2 heating pad burns, a burn from cooking, and a dog scratch.

Secondary Outcome Measures

On univariable regression analysis, there was no significant association between matrix type, age, radiation therapy, chemotherapy, or type of reconstruction (implant vs autologous) and complication rates. Obesity (body mass index $\geq 30\,kg/m^2$) was significantly associated with complications (odds ratio, 4.31, $P = 0.007$; Table 4). Bivariable regression analysis further demonstrated obesity to be an independent predictor of complications, whereas all the other variables remained nonsignificant predictors of complications (Table 5).

Table 1. BREASTrial Stage II Patient Demographics

Characteristics	AlloDerm (57 Patients, 91 Breasts)	DermaMatrix (54 Patients, 82 Breasts)	*P*
Age, y (range)	48 (25–75)	48 (29–82)	0.95
BMI, kg/m^2 (range)	27 (18–46)	27 (19–44)	0.98
Ethnicity (%)			0.61
White	56 (98.2)	52 (96.3)	
Asian	0 (0.0)	2 (3.7)	
Other	0 (0.0)	0 (0.0)	
Did not disclose	1 (1.8)	0 (0.0)	
Smoker	0 (0.0)	4 (7.4)	0.05
Diabetes	3 (5.3)	3 (5.6)	1
Chemotherapy (%)			0.02
Neoadjuvant	8 (14.0)	10 (18.5)	
Adjuvant	13 (22.8)	24 (44.4)	
None	36 (63.2)	20 (37.0)	
Postoperative XRT, no. of breasts (%)	16 (17.6)	28 (34.1)	0.01
Cancer present, no. of breasts (%)	45 (49.5)	47 (57.3)	0.36
Cancer stage (%)			0.15
0 in situ	10 (17.5)	5 (9.3)	
I	19 (33.3)	15 (27.8)	
II	5 (8.8)	6 (11.1)	
III	9 (15.8)	19 (35.2)	
IV	1 (1.8)	2 (3.7)	
Prophylactic	13 (22.8)	7 (13.0)	
Laterality (%)			0.45
Unilateral	23 (40.4)	26 (48.1)	
Bilateral	34 (59.6)	28 (51.9)	

BMI, body mass index; XRT, radiation therapy.

Table 2. BREASTrial Stage II Procedures

	All Breasts (%)	AlloDerm (%)	DermaMatrix (%)
Implant	130 (75.1)	73 (42.2)	57 (32.9)
Latissimus + implant	16 (9.2)	5 (2.9)	11 (6.4)
DIEP	15 (8.8)	9 (5.2)	6 (3.5)
TRAM	11 (6.4)	3 (1.7)	8 (4.6)
SIEA	1 (0.6)	1 (0.6)	0 (0)

There was no significant difference in the type of procedures performed between AlloDerm and DermaMatrix groups ($P = 0.09$).
DIEP, deep inferior epigastric perforator flap; Latissimus, latissimus dorsi flap; SIEA, superficial inferior epigastric artery flap; TRAM, transverse rectus abdominis flap.

DISCUSSION

The BREASTrial remains the largest trial to date in 2-stage immediate breast reconstruction utilizing ADM, and the only study that we are aware of that has prospectively studied 2 common types of ADM in a randomized, head-to-head fashion. Results of stage II of the trial demonstrate an acceptable complication profile in the early postoperative period (3 months) after definitive breast reconstruction with no differences between AlloDerm and DermaMatrix groups or between implant and autologous reconstruction groups. Although there were more patients who received chemotherapy and radiation therapy in the DermaMatrix by random chance in the study, regression analysis showed that chemotherapy/radiation therapy did not increase the risk of complications in the 3-month postoperative period in the overall cohort. This is counterintuitive since radiation therapy is known to be a risk factor for complications in breast reconstruction; however, since the follow-up is only 3 months in stage II for the trial, many of the complications may be yet to occur in the radiated cohort.

Table 3. BREASTrial Stage II Outcomes and Complications

	All Breasts (n = 173)	AlloDerm (n = 91)	DermaMatrix (n = 82)	*P*
Overall complications	29 (16.8%)	14 (15.4%)	15 (18.3%)	0.8
Mean complication grade	2.15	1.8	2.5	0.2
Major complications*	13 (7.5%)	5 (5.5%)	8 (9.6%)	0.2
Minor complications†	16 (9.2%)	9 (9.9%)	7 (8.5%)	0.5
Infection	8 (4.6%)	3 (3.3%)	5 (6.1%)	0.3
Wound separation	6 (3.5%)	4 (4.4%)	2 (2.4%)	0.2
Skin necrosis	5 (2.9%)	2 (2.2%)	3 (3.7%)	0.7
Implant loss	5 (2.9%)	2 (2.2%)	3 (3.7%)	0.5
Other‡	4 (2.3%)	2 (2.2%)	2 (2.4%)	0.7
Hematoma	1 (0.6%)	1 (1.1%)	0 (0%)	0.5
Seroma	0 (0%)	0 (0%)	0 (0%)	NA

Results of Fisher's exact (if $n \leq 5$) and chi-squared tests (if $n > 5$) for nominal variables (complication yes vs no) and Mann-Whitney U test for ordinal variables (complication grade 1–4) to compare differences in complications between groups.
*Major complications were those of grade 2 or more requiring hospitalization and/or surgical intervention.
†Minor complications required outpatient clinic treatment only.
‡Other included 3 burns and a dog scratch.
NA, not applicable.

Table 4. Univariate Regression Analysis for Complications

Predictors	Odds Ratio (95% CI)	*P*
ADM type (DM vs AD)	1.13 (0.41–3.09)	0.81
Age (per 10 y)	1.02 (0.66–1.59)	0.93
Obesity	4.31 (1.52–12.5)	0.007
Radiation	1.74 (0.61–4.97)	0.3
Chemotherapy	1.56 (0.56–4.35)	0.39
Recon type (implant vs autologous)	0.56 (0.19–1.63)	0.28

AD, AlloDerm; CI, confidence interval; DM, DermaMatrix.

It was not surprising that on regression analysis obesity was associated with increased complications in the trial, as obesity is a known risk factor for complications in breast reconstruction both with[3,4] and without[5] ADM. Although there was no direct association between obesity and an increased complication rate in stage I of the trial, we did discover that obesity was a predictor for poor ADM biointegration and longer drain time. These 2 factors were associated with increased complication rates, therefore conferring an indirect association between obesity and complications. This has led us to use ADM sparingly in the obese patient (body mass index $\geq 30\,kg/m^2$) in our breast reconstruction practice.

Regression analysis of stage II data showed no association between type of reconstruction (implant vs autologous) and complication rates. This finding is in contrast to recent data including a meta-analysis[6] that demonstrates decreased complication rates, less reconstructive failures, shorter time to complete reconstruction, and a trend toward lower costs for autologous breast reconstruction.[7] Our similar complication profile between autologous and implant-based reconstruction patients is likely because of short-term follow-up (3 months) and the fact that disease severity was higher and

Table 5. Bivariate Regression Analysis for Complications

	Additional Predictor		Obesity	
Additional Predictors	**Odds Ratio (95% CI)**	***P***	**Odds Ratio (95% CI)**	***P***
ADM type (DM vs AD)	1.15 (0.40–3.29)	0.79	4.34 (1.51–12.4)	0.007
Age (per 10 y)	0.98 (0.63–1.52)	0.93	4.34 (1.51–12.5)	0.007
Radiation	1.84 (0.62–5.51)	0.27	4.37 (1.51–12.6)	0.007
Chemotherapy	1.36 (0.47–3.92)	0.56	4.20 (1.47–12.0)	0.008
Recon type (implant vs autologous)	0.80 (0.25–2.57)	0.7	4.08 (1.37–12.2)	0.01

AD, AlloDerm; CI, confidence interval; DM, DermaMatrix.

there was more postoperative radiation therapy in the autologous reconstruction group. Subgroup analysis from the forthcoming stage III (2 year) follow-up data from the trial may further clarify these findings.

Despite a known association with increased complications rates,[8–10] ADM continues to be popular in breast reconstructive surgery. Advocates of ADM use in breast reconstruction cite decreased capsular contracture rates, decreased implant malposition, and improved aesthetic outcomes as advantages that potentially outweigh its risks.[11–13] One area of recent significant interest is utilizing ADM in immediate single-stage direct-to-implant breast reconstruction. Proponents to this approach have noted it to be cost-effective, to be safe, and to have a reasonable complication profile.[14–16] A current ongoing randomized trial comparing BREAST-Q and other outcomes between single-stage and 2-stage ADM breast reconstruction[17] should provide additional high level of evidence data to the current ADM breast reconstruction literature. Another area of recent interest in the literature is the use of terminally sterile ADMs, which may help mitigate the higher complication rates that ADM confers on breast reconstruction. However, a recent meta-analysis[18] and updated literature review[19] of sterile versus aseptic ADMs demonstrated no difference in complications rates. Randomized trials are needed to further define the benefit of sterile ADMs.

Limitations of the BREASTrial include lack of a total submuscular group, which would allow for a non-ADM control group comparison of the complications directly related to ADM. To date, only one other randomized trial has been completed that compared an ADM group with a total submuscular group.[20] This study focused mostly on pain outcomes and did not assess other outcomes of interest. The BREASTrial focused on comparing 2 commercially available and widely used ADMs of the time. New and improved products are coming to the market all the time including fenestrated, preshaped, and prehydrated ADMs. DermaMatrix has been superseded by its close sister product FlexHD Pliable (Musculoskeletal Transplant Foundation, Edison, N.J.). Our impression, based on this study, the current literature, and unpublished data from our laboratory, is that all ADMs perform similarly and that surgeons should choose the product that performs best in their hands. Use of nonbiologic meshes in breast reconstruction will also continue to evolve and may prove to be a cost-effective alternative to ADM in the future.

Another limitation of the study is that disparities exist between the 2 groups, even though patients were randomly assigned in a blinded fashion. The DermaMatrix group had more smokers, chemotherapy, and radiation therapy, even though overall cancer stage (0–IV) showed no statistical difference between groups ($P = 0.15$). There does appear to be a trend of more advanced disease (stage III–IV) in the DermaMatrix group, which makes type II error a possibility. This led to a trend of more autologous reconstruction in the DermaMatrix group. Disparities such as these were able to be accounted for in stage I of the trial through multivariable regression because of adequate power. In stage II of the trial, with fewer patients, and fewer complication events, there is not adequate power to correct for disparities or to perform robust subanalyses. However, the general outcome trends are still important to report and will assist plastic surgeons in making evidence-based decisions.

CONCLUSIONS

Stage II outcomes (from definitive reconstruction to 3 months postoperative) from the BREASTrial demonstrate a significant but acceptable complication profile. Similar to stage I, there were no differences in outcomes between AlloDerm and DermaMatrix groups. Although stage I data only demonstrated an indirect association between obesity and complications,[2] stage II data of 173 breasts revealed that obesity was directly associated with complications, whereas matrix type, age, chemotherapy, radiation therapy, and reconstruction type (autologous vs implant) were not.

ADM will likely continue to have a role in breast reconstructive surgery; however, caution should be taken when using ADM because of relatively high complication rates, especially in obese patients. The particular ADM product should be selected based on the individual surgeon preference, experience, and success rates. These data and forthcoming long-term outcomes from the BREASTrial will enable surgeons to carefully weigh the risks and benefits of ADM use in breast reconstruction.

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