The BREASTrial Stage III: Acellular Dermal Matrix Breast Reconstruction Outcomes from 3 Months to 2 Years Postoperatively

Shaun D. Mendenhall, MD[1]
Whitney D. Moss, BS[2]
Emily M. Graham, BSN[2]
Gentry Carter, BS[3]
Jayant P. Agarwal, MD[1]

Salt Lake City, UT

Background: The Breast Reconstruction Evaluation of Acellular Dermal Matrix as a Sling Trial (BREASTrial) is a blinded, randomized trial comparing the outcomes of tissue expander breast reconstruction using AlloDerm or DermaMatrix. In this final stage of the trial, outcomes 3 months to 2 years after definitive reconstruction are reported along with patient satisfaction data.
Methods: A randomized trial was conducted to compare complication rates between groups of patients who underwent reconstruction with AlloDerm and DermaMatrix. Regression models were used to analyze the impact of matrix type, age, chemotherapy, radiation therapy, and reconstructive type on complication rates. Premastectomy and postmastectomy questionnaires were used to assess patient satisfaction and were also analyzed using regression models.
Results: Of the 128 patients (199 breasts) who were randomized in the trial, 108 patients (167 breasts) were available for analysis in stage III. There was no difference in the overall complication rates between the AlloDerm and DermaMatrix groups (6% versus 13.2%; $P = 0.3$) or the severity of those complications ($P = 0.7$). Obesity was a positive predictor for complications, regardless of reconstruction group ($P = 0.02$). Patient satisfaction was positive overall and did not grossly vary between AlloDerm and DermaMatrix groups.
Conclusions: Findings from the BREASTrial conclude that AlloDerm and DermaMatrix exhibit similar histologic and clinical outcomes. Patient satisfaction is also similar between matrices. Obesity is a predictor of complications, and acellular dermal matrices should be used with caution in these patients. As the largest head-to-head trial comparing two acellular dermal matrices, the BREASTrial contributes to the fund of knowledge regarding acellular dermal matrix supplementation in breast reconstruction. (*Plast. Reconstr. Surg.* 151: 17, 2023.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

The Breast Reconstruction Evaluation of Acellular Dermal Matrix as a Sling Trial (BREASTrial) is the largest single-center, blinded, prospective, randomized trial comparing outcomes between two acellular dermal matrices, AlloDerm (LifeCell Corp., Branchburg, NJ) and DermaMatrix (Musculoskeletal Transplant Foundation, Edison, NJ, with marketing by Synthes, West Chester, PA), in staged breast reconstruction. The trial was divided into three

From the [1]Division of Plastic and Reconstructive Surgery, Department of Surgery, and [3]Department of Population Health Sciences, [2]University of Utah School of Medicine.
Received for publication July 9, 2021; accepted January 18, 2022.
This trial is registered under the name "The BREASTrial: Breast Reconstruction Evaluation Using Acellular Dermal Matrix as a Sling Trial," ClinicalTrials.gov identification no. NCT00872859 (http://clinicaltrials.gov/ct2/show/study/NCT00872859).
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DOI: 10.1097/PRS.0000000000009768

Disclosure: *The BREASTrial is an investigator-initiated study funded by grants from the University of Utah, Lifecell, Synthes, and the Musculoskeletal Transplant Foundation to Author Dr. Agarwal. Dr. Mendenhall is an educational consultant for PolyNovo and receives research funding from CoNextions Medical. No funding was received for this article. The remaining authors have no other financial conflicts of interest to declare in relation to this study.*

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outcome stages for ease of analysis and reporting: stage I, from the time of mastectomy and tissue expander placement to definitive reconstruction (tissue expansion phase); stage II, from the time of definitive reconstruction (autologous or implant-based) to 3 months postoperatively; and stage III, from 3 months to 4 years following definitive reconstruction. The trial design[1] and detailed outcomes from stage I[2] and stage II[3] were reported previously. Findings from stage I concluded that AlloDerm and DermaMatrix had similar complication profiles and that adjuvant treatment did not increase the risk of complications. However, the time to full expansion was nearly twice as long in the DermaMatrix group. Regardless of acellular dermal matrix type, obesity was also found to be an indirect predictor of complications. Stage II yielded similar findings, concluding that there was no significant difference in complication incidence or severity between acellular dermal matrix types and that obesity was directly correlated with increased complications.

In this final BREASTrial stage, study aims include overall complication rates and outcomes between AlloDerm and DermaMatrix groups. The relationship between complication rate and factors including age, diabetes, adjuvant therapy, and type of reconstruction will also be explored. Evaluating patient satisfaction, assessed through questionnaires distributed before and after mastectomy, is another important element of this study. As part of the head-to-head comparison between the two acellular dermal matrices, we hypothesized that there would be no significant differences in complication rates or severity. Based on stage I and II findings, we also hypothesized that obesity would significantly increase the risk for complication development. For patient satisfaction, we hypothesized that similar satisfaction scores would be observed regardless of acellular dermal matrix group, definitive reconstructive type (autologous or implant-based), or patient demographic factors.

PATIENTS AND METHODS

Study Design

Complete details of the study design and methods were published previously.[1] The trial received approval from the institutional review board and the clinical cancer investigations committee. In total, 128 patients (199 breasts) undergoing mastectomy and immediate tissue expander reconstruction at the University of Utah and Huntsman Cancer Institute were randomized into groups of patients who underwent reconstruction with AlloDerm or DermaMatrix. Tissue expansion proceeded, with outcomes reported previously.[2] Definitive reconstruction after expansion with a permanent prosthesis and/or autologous tissue was completed no sooner than 3 months after mastectomy, 3 weeks after the final chemotherapy dose, and 12 weeks after completion of radiation therapy. Patients who desired autologous reconstruction after expansion, required radiation therapy, or had skin necrosis/wound healing problems during stage I underwent autologous reconstruction. Otherwise, patients proceeded with implant-based reconstruction.

Outcome Measures

Primary outcome measures included the incidence and grade of complications for the entire cohort and in the AlloDerm and DermaMatrix groups during stage III. Secondary outcome measures included the impact of matrix type, age, obesity, radiation therapy, chemotherapy, and type of reconstruction (autologous versus implant-based) on complication rates. All complications were recorded and graded on a scale from 0 to 4 depending on the intervention required (0 = no intervention required; 1 = dressing changes, increased clinic visits or procedures; 2 = hospital admission, intravenous antibiotics, or pain control; 3 = surgical intervention in the operating room; and 4 = implant removal). Additional secondary outcomes included comparing nonstandardized, patient-reported preoperative and postoperative satisfaction data by reconstruction group (AlloDerm versus DermaMatrix, and autologous reconstruction versus prosthesis-only reconstruction versus latissimus flap and implant). (**See Appendix, Supplemental Digital Content 1**, which displays the premastectomy and postmastectomy patient satisfaction questionnaires and highlights the questions assessed in the satisfaction questionnaires, ***http://links.lww.com/PRS/F497***.)

Statistical Analysis

Statistical analyses were performed using R Statistical Software version 4.0.3 (Foundation for Statistical Computing, Vienna, Austria). To compare complications between groups, nominal variables (i.e., complication: yes versus no) were analyzed using chi-square tests, and ordinal variables (i.e., complication grade: 1 through 4) were analyzed using Fisher exact test. Multivariable logistic regression was performed to assess the effect of matrix type, age, obesity, radiation therapy,

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chemotherapy, and type of reconstruction on complication rates. Significant findings for all data were set with an alpha less than 0.05.

RESULTS

Patient Enrollment and Follow-Up

Of the 128 patients (199 breasts) who were randomized in the trial, 108 patients (167 breasts) were available for analysis in stage III, with similar numbers in each group (AlloDerm, 56 patients and 89 breasts; DermaMatrix, 52 patients and 78 breasts). In the AlloDerm group, two patients (three breasts) were lost to follow-up and one patient died as a result of disease during stage I. In the DermaMatrix group, three patients (six breasts) were lost to follow-up during stage I. During stage II, three patients (six breasts) were lost to follow-up, including one patient (two breasts) in the AlloDerm group and two patients (four breasts) in the DermaMatrix group (Fig. 1). The majority of patients were otherwise healthy, nonsmoking, and White. Complete patient demographic details were published previously.[1] Satisfaction data were gathered both preoperatively and at 2 years postoperatively from 70 patients (AlloDerm, 33 patients; DermaMatrix, 37 patients).

Primary Outcome Measures

Overall complication rate for stage III was 9.6%, with 40% of those complications requiring inpatient and/or operative management. Of note, no implants were lost or removed during this stage. When analyzing differences between the AlloDerm and DermaMatrix groups, there was no difference in overall rates of complications (6% versus 13.2%; $P = 0.3$), or the severity of those complications (66.7% versus 57.1% for grade I complications, 0% versus 14.3% for grade II complications, and 33.3% versus 28.6% for grade III complications; $P = 0.4$) between the AlloDerm and DermaMatrix groups (Table 1).

Secondary Outcome Measures

A multivariable logistic regression model showed no significant association between matrix type ($P = 0.52$), age ($P = 0.32$), adjuvant therapy ($P = 0.85$), or type of reconstruction (autologous versus implant-based) ($P = 0.10$) on complication rates. Obesity was significantly associated with complications ($P = 0.02$) (Table 2). A Hosmer-Lemeshow goodness-of-fit test showed no evidence of poor fit ($P = 0.8$).

Multivariable linear regression analysis revealed no significant differences between AlloDerm and DermaMatrix groups on the patient-reported premastectomy or postmastectomy questionnaires. However, multivariable linear regression analysis showed that the DermaMatrix group reported significantly higher satisfaction on question 6 (maintained/increased patients' feminine appearance) on the postmastectomy questionnaire ($P < 0.02$). Age also significantly influenced satisfaction scores on the postmastectomy questionnaire. For every 10 years older a patient was, satisfaction scores increased by one-third of a point on questions 3 (rechoosing to undergo reconstruction), 4 (rechoosing the same type of reconstruction), and 5 (recommending the same type of reconstruction to a friend) ($P = 0.02$, $P < 0.001$, and $P < 0.001$, respectively). Postmastectomy satisfaction was unaffected by the patient's obesity status (body mass index >35 kg/m^2), diabetes status, surgical laterality (unilateral versus bilateral), and whether the patient received adjuvant therapy (Table 3).

DISCUSSION

The BREASTrial remains the largest randomized trial to prospectively compare two acellular dermal matrices in a head-to-head fashion during two-stage autologous and implant-based breast reconstruction. The overall complication rate for the entire cohort was 9.6%. This is substantially lower than the short-term complication rate reported in stage II, and is also lower than trials with similarly designed, 2-year follow-up after breast reconstruction.[3–5] Importantly, these data demonstrate that most complications occur in the early postoperative period from expansion to approximately 3 months, which is a possible explanation of why complication rates were higher during stage I and stage II of this trial.

It is unclear whether these long-term complication rates are generalizable, or whether these positive findings are a consequence of the trial occurring at a single center with a homogeneous population. Individual surgeon and institutional complication rates and trends should be compared to the results from the BREASTrial to determine generalizability. Like other BREASTrial reports, there were no significant differences in the rate or severity of complications between AlloDerm and DermaMatrix, despite the DermaMatrix group containing more tobacco users and patients who received radiation therapy. Perhaps a decreased complication rate in the group of patients who

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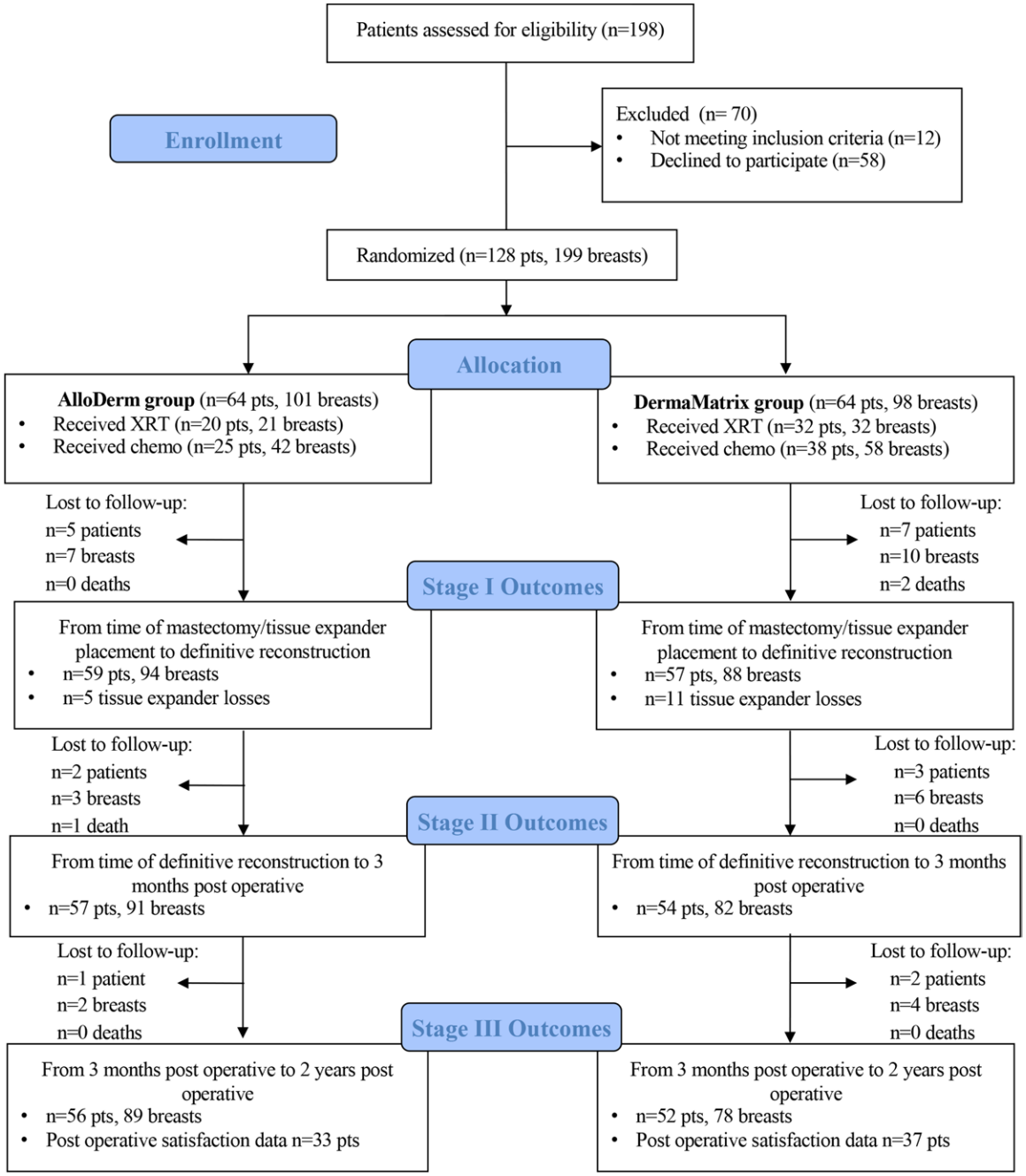

Fig. 1. BREASTrial flowchart and final outcome by stage. *Pts*, patients; *XRT*, radiation therapy; *chemo*, chemotherapy. (Flowchart template from Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol*. 2010;63:834–840.)

underwent reconstruction with DermaMatrix would have been appreciated without these differences.[1,2] Supporting this potential limitation are the histologic results from the BREASTrial biopsy specimens, which showed that groups of patients who underwent reconstruction with DermaMatrix experienced less of an inflammatory response compared to those who underwent reconstruction with AlloDerm.[6]

Obesity was a reliable predictor of developing a complication, regardless of acellular dermal matrix type or reconstruction method. This finding is consistent with findings from stage II.[3] In stage I, obesity was associated with increased drain duration and poor acellular dermal matrix biointegration, factors also positively correlated with complication development.[2] These collective findings from the BREASTrial

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Table 1. BREASTrial Stage III Complications

	All Breasts (%)	AlloDerm (%)	DermaMatrix (%9	*P*
No. of breasts	167	89	78	
Overall complications	10 (9.6)	3 (6)	7 (13.2)	0.3
Mean complication grade	1.7	1.6	2	0.4
Grade I complications	6 (60)	2 (66.7)	4 (57.1)	
Grade II complications	1 (10)	0 (0)	1 (14)	
Grade III complications	3 (30)	1 (33.3)	2 (28.6)	

Table 2. Multivariable Logistic Regression Analysis for Complications

Predictor	OR (95% CI)	*P*
ADM type (DM vs. AD)	1.67 (0.34–9.52)	0.52
Age (per 10 yr)	1.02 (0.97–1.09)	0.32
Obesity	1.14 (1.02–1.29)	0.02[a]
Adjuvant therapy	0.84 (0.17–4.23)	0.85

ADM, acellular dermal matrix; DM, DermaMatrix; AD, AlloDerm.
[a]Statistically significant.

support that obesity may be an accurate predictor of postoperative complications in the setting of breast reconstruction with acellular dermal matrix use. Others report similar observations and note that acellular dermal matrix presence is relevant to complication risk in obese patients.[7–9] These observations led our reconstructive breast practice to use acellular dermal matrix with caution in obese patients and to enrich our preoperative informed consent to reflect these increased risks.

Another aspect analyzed in this arm of the BREASTrial were patient-reported premastectomy and postmastectomy breast reconstruction patient satisfaction questionnaires (**see Appendix, Supplemental Digital Content 1**, ***http://links.lww.com/PRS/F497***). These questionnaires were developed at our institution before the popularization of the BREAST-Q[10] and the BRECON-31.[11] Similar to these validated satisfaction scores, the questionnaires used in this trial assessed overall satisfaction, surgeon communication before and after mastectomy, and quality of life after reconstruction. Grossly, there were no significant differences in satisfaction between groups of patients who underwent reconstruction with AlloDerm or DermaMatrix. This supports previous literature findings that type of acellular dermal matrix does not affect patient-reported outcomes.[12–14] Age significantly influenced several satisfaction scores in the postmastectomy questionnaire, with older patients reporting higher levels of satisfaction. Specifically, older patients reported more satisfaction with overall choice of undergoing breast reconstruction, which type of breast reconstruction they chose, and in confidence of recommending the same type of reconstruction to a friend. Although these findings require further exploration and are likely multifaceted, it may be worth mentioning this to patients during the informed consent process.

Innovations in breast reconstruction continue to expand the surgical options available to plastic surgeons and patients. Variations in timing after mastectomy with one- or two-stage reconstructions, anatomical plane selection, and supplementation with acellular dermal matrix are currently debated among experts.[15] A distinguishing aspect to the BREASTrial is the exclusive use of a two-stage, subpectoral, autologous or implant-based reconstruction using one of two popular acellular dermal matrices. As single-stage reconstruction grows in popularity, advantages of the approach are better documented, including improved cost benefits and lower anesthesia-related risks, and consequence of eliminating a secondary operation.[16,17] However, others note increased risk of infection, seroma, and skin necrosis in patients during one-stage reconstruction and thus continue to advocate for two-stage reconstruction.[18–20] To our knowledge, there have been no head-to-head, randomized controlled trials comparing one- versus two-stage reconstruction complication rates, and further exploration is warranted. Regardless, acellular dermal matrix is generally used in either method of reconstruction. This trial specifically supports two-stage reconstruction as a safe approach, as the overall complication rates were low among our cohort and histologic results were similar between acellular dermal matrices.[6] Ultimately, patient preference and surgeon expertise should be used during preoperative planning, as both approaches have benefits and drawbacks.

Anatomical plane selection has continued to evolve since the inception of the BREASTrial. All patients in the trial underwent reconstruction using a partial submuscular approach, and although this approach has been the standard of care,[21,22] there is now the option for reconstruction to include either total submuscular or prepectoral planes, although they are not without

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Table 3. Multivariable Linear Regression Analysis of Postoperative Satisfaction Questionnaire Questions

Variable	Effect Size (95% CI)	*P*
ADM type (DM vs. AD)		
Q1: satisfied with reconstruction	−0.43 (−1.09 to 0.23)	0.19
Q2: postoperative expectations were set well	−0.51 (−1.25 to 0.23)	0.17
Q3: would choose reconstruction again	−0.44 (−0.96 to 0.07)	0.09
Q4: would choose same type of reconstruction again	−0.17 (−0.73 to 0.38)	0.53
Q5: would recommend same type of reconstruction to a friend	−0.19 (−0.77 to 0.39)	0.51
Q6: reconstruction maintained/increased feminine appearance	−0.86 (−1.56 to −0.16)	0.02[a]
Q7: comfortable showing breasts to others	−0.29 (−1.05 to 0.47)	0.45
Age (by each increase in 10 yr)		
Q1: satisfied with reconstruction	−0.01 (−0.04 to 0.02)	0.41
Q2: postoperative expectations were set well	−0.01 (−0.05 to 0.02)	0.49
Q3: would choose reconstruction again	−0.03 (−0.05 to 0.00)	0.02[a]
Q4: would choose same type of reconstruction again	−0.03 (−0.06 to −0.01)	0.01[a]
Q5: would recommend same type of reconstruction to a friend	−0.04 (−0.07 to −0.1)	<0.01[a]
Q6: reconstruction maintained/increased feminine appearance	0.00 (−0.3 to 0.04)	0.79
Q7: comfortable showing breasts to others	0.00 (−0.04 to 0.03)	0.87
Obesity (BMI >35 kg/m^2)		
Q1: satisfied with reconstruction	−0.01 (−0.08 to 0.06)	0.80
Q2: postoperative expectations were set well	0.00 (−0.08 to 0.07)	0.95
Q3: would choose reconstruction again	0.00 (−0.05 to 0.05)	0.98
Q4: would choose same type of reconstruction again	0.01 (−0.05 to 0.06)	0.87
Q5: would recommend same type of reconstruction to a friend	0.00 (−0.06 to 0.06)	0.92
Q6: reconstruction maintained/increased feminine appearance	−0.02 (−0.09 to 0.05)	0.56
Q7: comfortable showing breasts to others	0.01 (−0.07 to 0.09)	0.84
Diabetes status		
Q1: satisfied with reconstruction	−1.10 (−2.37 to 0.18)	0.09
Q2: postoperative expectations were set well	−0.68 (−2.11 to 0.75)	0.34
Q3: would choose reconstruction again	−0.72 (−1.71 to 0.27)	0.15
Q4: would choose same type of reconstruction again	−0.71 (−1.78 to 0.36)	0.19
Q5: would recommend same type of reconstruction to a friend	−0.86 (−1.98 to 0.26)	0.13
Q6: reconstruction maintained/increased feminine appearance	−0.71 (−2.06 to 0.64)	0.30
Q7: comfortable showing breasts to others	−0.57 (−2.03 to 0.90)	0.44
Adjuvant therapy (recipient vs. not)		
Q1: satisfied with reconstruction	−0.05 (−0.73 to 0.63)	0.88
Q2: postoperative expectations were set well	0.12 (−0.65 to 0.88)	0.76
Q3: would choose reconstruction again	0.20 (−0.32 to 0.73)	0.44
Q4: would choose same type of reconstruction again	−0.02 (−0.60 to 0.55)	0.94
Q5: would recommend same type of reconstruction to a friend	0.03 (−0.56 to 0.63)	0.91
Q6: reconstruction maintained/increased feminine appearance	0.19 (−0.53 to 0.90)	0.60
Q7: comfortable showing breasts to others	0.15 (−0.63 to 0.93)	0.71
Surgical laterality (unilateral vs. bilateral)		
Q1: satisfied with reconstruction	0.46 (−0.21 to 1.13)	0.17
Q2: postoperative expectations were set well	−0.07 (−0.82 to 0.68)	0.85
Q3: would choose reconstruction again	−0.25 (−0.77 to 0.27)	0.33
Q4: would choose same type of reconstruction again	−0.05 (−0.61 to 0.52)	0.87
Q5: would recommend same type of reconstruction to a friend	−0.14 (−0.72 to 0.45)	0.64
Q6: reconstruction maintained/increased feminine appearance	0.05 (−0.66 to 0.75)	0.89
Q7: comfortable showing breasts to others	−0.30 (−1.06 to 0.47)	0.44

ADM, acellular dermal matrix; DM, DermaMatrix; AD, AlloDerm; Q, question; BMI, body mass index.
[a]Statistically significant.

their own accompanying risks.[18–20] The reported risks when using a partial submuscular plane approach can include increased duration of postoperative drains; increased postoperative pain; and long-term complications, including animation deformity.[20,23] These associated sequelae may have indirectly influenced complication rates and patient satisfaction scores in the BREASTrial. It is documented that surgeons managing patients with particularly small breasts, poorly vascularized or thin skin, or local radiation damage should consider a partial submuscular approach.[23]

Even as other aspects of breast reconstruction are changing and debated, supplementing breast reconstruction with acellular dermal matrix remains popular. Acellular dermal matrix use is associated with decreased capsular contracture rates, increased soft-tissue support, and enhanced aesthetic outcomes.[24–26] These advantages often outweigh the risks. However, despite their use for more than two decades, use of acellular dermal matrix in breast reconstruction was recently deemed as an "off-label" use by the U.S. Food and Drug Administration in 2019.[27] Surgeons planning to incorporate acellular dermal matrix in reconstruction should discuss this change with patients before surgery as part of the informed consent process, although they should also note

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that this change did not occur because of poor product performance.[28] As mentioned in previous stages of this study, the acellular dermal matrices used in this trial have since undergone modifications to improve usability. Although it is unlikely these modifications would produce dramatic changes clinically, this limitation should also be considered when analyzing the BREASTrial.

In this final stage of the BREASTrial, patient outcomes 3 months to 2 years after definitive reconstruction were analyzed along with patient satisfaction data. The overall complication risk was low, with the majority of complications rated as mild. There was no difference in the incidence or severity of complications between groups of patients who underwent reconstruction with AlloDerm and DermaMatrix. Consistent with previous BREASTrial reports, obesity was a positive predictor of complications. Surgeons should consider using acellular dermal matrix with caution and enriching the preoperative consent process to reflect the increased risks in this population. Patient satisfaction scores before and after mastectomy were positive and did not vary between groups of patients who underwent reconstruction with AlloDerm or DermaMatrix. However, older patients reported higher satisfaction overall with their breast reconstruction, and perhaps this should be shared when counseling patients about the decision to undergo reconstruction.

CONCLUSIONS

Findings from the BREASTrial stages I to III indicate that AlloDerm and DermaMatrix exhibit similar histologic and clinical outcomes. Similarities in product performance support surgeons selecting acellular dermal matrix based on preference and cost. Caution should still be exercised when performing reconstruction with acellular dermal matrix, particularly in obese patients, as they have an increased risk of developing a complication. As the largest head-to-head, prospective, randomized controlled trial comparing two acellular dermal matrices, the BREASTrial contributes to the fund of knowledge regarding acellular dermal matrix supplementation in breast reconstruction.

Jayant P. Agarwal, MD
Division of Plastic and Reconstructive Surgery
University of Utah School of Medicine
30 North 1900 East, 3B400
Salt Lake City, UT 84132
jay.agarwal@hsc.utah.edu

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