Published in final edited form as:

Plast Reconstr Surg. 2018 December ; 142(6): 1401–1409. doi:10.1097/PRS.0000000000004968.

Immediate Implant-Based Breast Reconstruction with Acellular Dermal Matrix: A Comparison of Sterile and Aseptic AlloDerm in 2039 Consecutive Cases

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Abstract

Background: Sterile, ready-to-use acellular dermal matrix (RTU ADM), introduced as an alternative to aseptic, freeze-dried acellular dermal matrix (FD ADM) for implant-based breast reconstruction (IBR), has been investigated in a limited number of studies. The purpose of this study was to compare outcomes in IBR with RTU ADM and FD ADM.

Methods: We analyzed patients undergoing IBR with either FD ADM or RTU ADM, including demographics, clinical variables, and outcomes. An *a priori* power analysis was performed and logistic regression modeling was used to quantify the effect of ADM on outcomes while controlling for potential confounders.

Results: 1285 consecutive patients undergoing 2039 immediate prosthetic breast reconstructions comprised the population: 612 (n=910 breasts) with FD ADM and 673 (n=1129 breasts) with RTU ADM. The FD ADM cohort had a significantly higher rate of explantation compared to RTU ADM cohort (18.0% versus 12.0%, $p = 0.0036$), but surgical site infection, wound dehiscence, mastectomy flap necrosis, seroma, and hematoma did not differ significantly between groups. On multivariate regression, patients having reconstruction with FD ADM, compared to RTU ADM, did not have higher odds of experiencing surgical site infections (OR 1.064, $p = 0.7455$), but did have higher odds of explantation (OR 1.570, $p = 0.0161$). Tobacco use (OR 2.809, $p = 0.0002$) and BMI (OR 1.054, $p < 0.0001$) were also independent predictors of explantation.

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Conclusions: Immediate implant-based breast reconstruction with sterile, RTU ADM has a comparable overall safety profile, and a lower rate of prosthetic explantations, compared to aseptic, FD ADM.

INTRODUCTION

Breast cancer remains the most common non-cutaneous cancer among women in the United States, with an estimated 252,710 new cases diagnosed in 2017.(1) Among techniques for postmastectomy breast reconstruction, implant-based (prosthetic) breast reconstruction remains the most prevalent with utilization expanding by 11% annually compared to autologous breast reconstruction.(2) Acellular dermal matrices (ADM), utilized for inferolateral pole coverage of the prosthetic device,(3, 4) remain a common adjunct technique for implant-based breast reconstruction. Reported advantages of ADMs for prosthetic breast reconstruction include decreased time necessary to complete reconstruction, more consistent and natural appearing aesthetic results, decreased manipulation of the chest wall musculature, and improved soft-tissue support facilitating, in some cases, immediate, direct-to-implant reconstruction.(5–7) However, ADM use in breast reconstruction is not without disadvantages, with some prior studies demonstrating increased rates of seroma, inflammatory reactions, and infectious complications compared to total submuscular coverage.(8–10)

Multiple different ADM products are now available with varying data available to support their safety and efficacy.(11–17) The most commonly used and studied ADM, AlloDerm Regenerative Tissue Matrix (LifeCell Corporation, Allergan, Dublin, Ireland) was originally available commercially as freeze-dried AlloDerm (FD ADM).(18) In 2010, AlloDerm sterile, ready-to-use (RTU) was introduced as an alternative option to the aseptic form, with the purported advantages being improved sterility and expedited intraoperative processing (two minutes versus 30 minutes of rehydration for aseptic ADM). The Food and Drug Administration (FDA) classifies AlloDerm as human tissue for transplantation. Both FD and RTU ADM achieve a sterility assurance level of 10^{-3} , but are differentiated by a terminal sterilization process set forth by the FDA that sterile RTU ADM undergoes, but aseptic FD ADM does not. While it is reasonable to expect RTU ADM to have equivalent, if not favorable, clinical outcomes over aseptic FD ADM, there are limited data available to confirm this hypothesis. The few studies evaluating the safety and efficacy of AlloDerm RTU report conflicting results regarding complications like infection, explantation, and seroma.(19–22) Unfortunately, these prior studies have been limited by small sample sizes, precluding the ability to adequately control for confounding variables.(18, 20) In fact, across all four prior studies on the topic, study populations ranged from 58 patients to 122 patients, resulting in a total population in the literature of only 364 patients.(19, 21–23) It is integral as technology evolves that new products undergo the same rigorous evaluation as their predecessors to ensure comparable safety and outcomes. Therefore, the purpose of this study was to compare clinical outcomes and complications, leveraging multivariable regression modeling to control for confounding variables, in women undergoing immediate implant-based breast reconstruction with RTU ADM and FD ADM. We hypothesize that RTU ADM is associated with fewer infections and explantations than FD ADM.

MATERIALS AND METHODS

This study retrospectively analyzes a prospectively-maintained database of all patients undergoing implant-based breast reconstruction at the Siteman Cancer Center in Saint Louis. With institutional review board approval (# 201106126), all consecutive patients undergoing immediate postmastectomy implant-based breast reconstruction by three plastic surgeons (TMM, MMT, KEB) over an 11-year period, from January 2005 to December 2015, were identified. Mastectomy procedures were performed by a total of six breast surgeons. All patients had at least two years of follow-up, with patients receiving ADM FD undergoing immediate reconstruction from 2005 to 2010, and those receiving ADM RTU from 2010 to 2015. Inclusion criteria were patients more than 18 years old, patients undergoing immediate breast reconstruction with a staged tissue-expander/implant approach or a direct-to-implant approach, and patients undergoing reconstruction with placement of either RTU or FD ADM. Exclusion criteria included patients undergoing delayed implant-based breast reconstruction, without use of ADM, reconstructions performed by other plastic surgeons, ADM or mesh product other than AlloDerm RTU or FD, prepectoral reconstructions, concomitant autologous flap, and patients with inadequate follow-up.

Prosthetic devices included in this study were anatomic or round and smooth or textured devices that were on consignment at our hospital. All tissue expanders used in tissue expander/implant reconstructions were Allergan (Allergan, Inc., Dublin, Ireland) 133 MV devices. Implants used at the time of permanent implant-exchange or in direct-to-implant reconstructions were either Allergan or Sientra (Sientra, Inc., Santa Barbara, CA) devices. Consistent techniques were utilized throughout the study period with prosthetic devices placed in a partial submuscular plane following elevation of the pectoralis major muscle and ADM utilized for coverage of the lower pole as an inferolateral sling with either a nonperforated 8 × 16 cm sheet for tissue expander or a 10 × 20 cm sheet for direct-to-implants. Two closed-suction drains, one superficial and one deep to the ADM were placed on each side and removed when output was less than 30 cc over a 24 hour period. All patients received preoperative antibiotics per ASPS Clinical Practice Guidelines and perioperative antibiotics until drain removal.(24)

Data and Statistical Analysis

Demographic and clinical data, including age, race, body-mass index (BMI), patient comorbidities, smoking status, exposure to radiation therapy, exposure to adjuvant/neoadjuvant chemotherapy, use of endocrine therapy, cancer stage, laterality (unilateral versus bilateral) of reconstruction, indication for mastectomy (prophylactic or therapeutic), type of mastectomy (nipple-sparing, skin-sparing, or modified radical), type of reconstruction (tissue expander/implant versus direct-to-implant) were recorded. Postoperative clinical outcomes, including seroma, hematoma, surgical site infection requiring intravenous antibiotics, explantation, wound dehiscence, mastectomy flap necrosis, and implant problems were recorded. Implant problems were defined as implant exposure, malposition, deflation, or rupture. A particular patient may have had more than one outcome as would be the case, for example, if an exposed implant was explanted due to a wound dehiscence. The primary clinical outcomes were surgical site infection requiring intravenous

antibiotics, prosthetic explantation, and presence of any surgical complication postoperatively. Explantation was defined as unplanned removal of the prosthetic device for any reason. Indications for unplanned explantation included infection, persistent seroma unresponsive to drainage interventions, device exposure, or pending exposure due to comprised soft tissue coverage.

Statistical analyses were performed using SAS software (Version 9.4, SAS Institute Inc., Cary, NC). An *a priori* power analysis to estimate appropriate sample size indicated 359 to 612 patients would be required per group assuming a baseline difference in primary outcome of 6–8%, with 80% power and significance level of $\alpha = 0.05$. Summary descriptive statistics were first tabulated. For continuous variables, mean and standard deviations are presented. For categorical variables, the number and proportion of study subjects in each level of categorical variable is presented. Chi-squared analyses were used to compare categorical variables of interest. If the expected count of any subgroup was five or less, Fisher's exact test was used instead. For categorical variables with more than two subgroups, if the overall Chi-squared test indicated a statistically-significant difference, then individual Chi-squared tests were run against each subgroup to identify which specific subgroup was significantly-different, with Bonferroni's correction applied to the level of statistical significance to account for multiple testing. Student's *t*-test was used to compare continuous variables of interest. Logistic regression modeling was used to quantify the effect of the type of ADM on the three primary outcomes while controlling for potential confounders. To be included in the multivariate analysis, potential confounders had to exhibit $p < 0.010$ on univariate logistic regression. Final results are reported as adjusted odds ratios (OR) with confidence intervals (CI). $\alpha = 0.05$ indicated significance in all tests.

RESULTS

A total of 1285 patients who underwent 2039 immediate implant-based breast reconstructions after mastectomy were evaluated once inclusion and exclusion criteria were applied to an original cohort of 1846 patients. Patients were separated into two clinical cohorts: those undergoing breast reconstruction with aseptic FD ADM (612 patients; 910 breasts) and those undergoing breast reconstruction with sterile RTU ADM (673 patients; 1129 breasts). Demographic and clinical characteristics between the two cohorts were compared (Table 1). The groups were statistically similar ($p > 0.05$) in regards to age, BMI, current tobacco use, diabetes, adjuvant radiation and endocrine therapy. Patients in the RTU ADM group were significantly more likely to have prior chest wall radiation (5.9% versus 0.7%, $p < 0.0001$), prophylactic mastectomy (7.3% versus 0.0%, $p < 0.0001$), nipple-sparing mastectomy (21.4% versus 1.0%, $p < 0.0001$), undergo bilateral procedures (67.8% versus 48.7%, $p < 0.0001$), and have direct-to-implant reconstruction (9.4% versus 0.0%, $p < 0.0001$). Contrastingly, patients in the FD ADM group were significantly more likely to undergo neoadjuvant (29.9% versus 22.6%, $p < 0.0001$) and adjuvant (42.8% versus 28.9%, $p < 0.0001$) chemotherapy.

There were no statistically significant differences between the RTU and FD ADM cohorts for the complications of surgical site infection, wound dehiscence, mastectomy flap necrosis, implant problems, seroma, and hematoma (Table 2). However, the FD ADM cohort had a

significantly higher rate of explantation compared to the RTU ADM cohort (18.0% versus 12.0%, $p = 0.0036$).

On univariate logistic regression, covariates significantly associated with the primary outcomes were identified and included in the multivariate logistic regression model. Adjusted odds ratios with 95 percent confidence intervals and p-values are reported in Tables 3, 4, and 5 for the impact of these covariates on the primary outcomes surgical site infection, explantation, and complications. On multivariate logistic regression, BMI was the only variable that independently predicted occurrence of surgical site infection (OR 1.039, 95% CI: 1.012 – 1.066, $p = 0.0037$). Patients having reconstruction with FD ADM did not have a significantly higher odds of experiencing surgical site infections compared to patients having reconstruction with RTU ADM (OR 1.064, 95% CI: 0.732 – 1.546, $p = 0.7455$). For the outcome explantation, three variables were independent predictors on multivariate logistic regression analysis. These included aseptic FD ADM (OR 1.570, 95% CI: 1.087 – 2.267, $p = 0.0161$), current smoking (OR 2.809, 95% CI: 1.916 – 4.115, $p = 0.0002$), and BMI (OR 1.054, 95% CI: 1.030–1.079, $p < 0.0001$). Independent predictors for occurrence of any complication on multivariate logistic regression were current smoking (OR 2.053, 95% CI: 1.458 – 2.899, $p = 0.0047$), adjuvant radiation therapy (OR 1.980, 95% CI: 1.016 – 3.984, $p = 0.0059$), and BMI (OR 1.047, 95% CI: 1.026 – 1.069, $p < 0.0001$).

DISCUSSION

ADM use in implant-based breast reconstruction procedures has evolved considerably since initial reports.(2) While multiple subsequent studies have evaluated the utility and safety of ADM use in immediate breast reconstruction, a majority of these focused on FD ADM.(18) As technology and the market for ADM expanded, novel products have been introduced into clinical practice and purported to have the same, or even an improved, safety profile as the original FD ADM. One such product is RTU ADM. While increasingly used clinically, to date, there has been minimal evidence to corroborate the comparative complication and safety profile of RTU ADM versus the original FD ADM. Demonstrating the safety and efficacy of disparate operative techniques and technologies is critical to ensuring continued quality improvement in implant-based breast reconstruction. In this study, we demonstrated immediate implant-based breast reconstruction with RTU ADM resulted in a significantly lower rate of prosthetic explantation compared to reconstruction with FD ADM while maintaining a similar complication profile in regards to overall complication rates, noninfectious wound healing complications, surgical site infections, and seromas/hematomas. Of importance, we also demonstrated use of FD ADM was an independent predictor of explantation complications in immediate implant-based breast reconstruction. Taken comprehensively, the results of our study confirm the overall safety and efficacy of RTU ADM use as an adjunct to implant-based breast reconstruction procedures and suggest RTU ADM has clinical advantages over FD ADM, including accelerated rehydration time and significantly lower explantation rates.

This study of 1285 patients undergoing 2039 immediate implant-based breast reconstructions is the largest consecutive series in the literature to evaluate clinical outcomes for two disparate types of ADM. Our work builds on that of prior authors and expands the

literature on the topic of sterile versus aseptic ADM use in implant-based breast reconstruction. In 2013, Weichman et al. reported their experience with aseptic FD ADM and sterile RTU ADM in 345 consecutive patients, demonstrating a decreased rate of surgical site infections and explantations in the RTU cohort versus the FD cohort.(21) Similarly, Lewis et al. reported lower rates of infection and wound necrosis with RTU ADM versus FD ADM in a series of 105 patients in 2015.(23) However, contrastingly, Buseman et al. published a series of 34 patients reconstructed with RTU or FD ADM and showed a higher rate of seroma in the RTU ADM group and no differences in infectious complications.(19) Similarly, in 2014, Yuen et al. also reported higher complication rates for seroma and cellulitis in RTU ADM reconstructions compared to FD ADM reconstructions in a series of 103 patients.(22) Unfortunately, while providing valuable preliminary data on the topic, these studies were limited by small sample sizes that precluded adequately controlling for confounding clinical variables or identifying significant differences in clinical outcomes between study groups. Ultimately, the inconsistent results across these studies and methodological limitations have made it difficult for clinicians to determine the relative value of RTU ADM in comparison to FD ADM as an adjunct to immediate implant-based breast reconstruction procedures.(20) The strengths of our study are the large sample size, the ability to evaluate for independent predictors of the primary outcomes using multivariable logistic regression analyses, the ability to control for confounding variables in the analyses, and a two-year minimum follow-up period to evaluate outcomes in all study patients.

There are several findings in this study that merit discussion. We did not find statistically significant differences in infectious complications between the RTU and FD ADM cohorts (10.4% versus 11.3%, $p = 0.6075$). Also, aseptic ADM use was not an independent predictor of surgical site infections in our series (OR 1.064, 95% CI: 0.732–1.546, $p = 0.746$). One of the main reported advantages of RTU ADM is the terminal sterilization process which theoretically could reduce the rate of surgical site infections compared to the aseptically processed FD ADM. In our study, this theoretical advantage was not substantiated by the data. Our overall rate of surgical site infections is consistent with prior reports in the literature.(25–28) Without question, eliminating this prosthesis as a source of bacterial contamination is critical, and understandably is a focus of vendors who provide ADMs.(11, 29) The breast, however, is not an innocent bystander as it is contaminated with its own bacterial microbiome(30) that is more diverse than the skin,(31) and can vary based on patient demographics,(32) and a breast cancer diagnosis.(31, 33)

Explantation rates were relatively high in our study, and were predicted by FD versus RTU ADM use, smoking, and BMI. We included all prosthetic explantations (tissue expander or implant) in our data and captured outcomes out to a minimum of two years after initial reconstruction. When accounting for this length of follow-up, our complication rates are similar to recent studies in the literature.(28, 34) In recent studies published from the Mastectomy Reconstruction Outcomes Consortium (MROC) with two-year outcomes data, the rate of major complications requiring rehospitalization and/or reoperation were 22.4% in patients undergoing implant-based reconstruction with ADM and the rates of reconstructive failure ranged from 3.7% to 18.7%.(28, 34) Further, in our series, 20.3% of women in the FD ADM and 15.2% in the RTU ADM groups were current smokers (Table 1), dramatically

higher than the 2.4% incidence of smokers in the series reported by Srinivasa et al. (35) and 5.7 to 6.7% by Weichman et al.(21) According to the most recent report from the Centers for Disease Control and Prevention, our data is consistent with the general population where, in 2015, 17% of women from 25 to 65 years of age, and particularly those in the Midwest, smoked.(36) In addition, mean BMI in our series was 28.3 ± 5.1 , significantly higher than that reported in other large series evaluating immediate prosthetic breast reconstruction.(21, 35, 37) Again, our data may be more reflective of the general population as the most recent comprehensive national report on obesity indicates that 30–35% of white, and >35% of African American women have a BMI greater than 30.(38) While we have traditionally made every attempt to offer immediate breast reconstruction to patients following mastectomy, treating this population differently than those seeking elective cosmetic surgery, we acknowledge that this has a potentially higher risk for complications. To limit this for high risk patients, we now more strongly promote delayed reconstruction to limit complication rates.(26, 37, 39, 40)

Compared to RTU ADM, our data suggest an association between FD ADM and significantly higher rates of explantation in the absence of concomitant increases in other complications typically associated with higher explantation rates such as surgical site infection, wound dehiscence, or mastectomy flap necrosis. This discrepancy may be due to several factors. Wound dehiscence and mastectomy flap necrosis rates, both of which can lead to overt or imminent device exposure, were noticeably higher in the FD ADM group (Table 2) but did not, independently, achieve statistical significance. While our analysis controlled for other potential confounding differences between the FD and RTU ADM cohorts like cancer stage, BMI, and smoking, (Table 1) we did not control for factors such as flap thickness, surgical oncologist, initial fill volumes, and the impact of clinical experience with tissue expander reconstruction supplemented with an ADM sling. The RTU ADM group may have benefited from changes in surgical approach that were derived from operator experience including initial fill volumes, ability to judge skin perfusion clinically with or without adjunctive imaging technology, and behaviors including the tendency to watch versus explant a tissue expander from an infected versus potentially only inflamed red breast. Later in the series, RTU ADM may have undergone nipple-sparing mastectomy and direct-to-implant reconstructions. So, while on the one hand, the RTU ADM patients may have benefited from our extensive experience with FD ADM, skin-sparing mastectomies and tissue-expander reconstruction, on the other, they were susceptible to the learning curve associated with nipple-sparing mastectomy and direct-to-implant reconstructions. In this retrospective study design, we cannot rule out an element of selection bias. Patients deemed unfavorable candidates for prosthetic reconstruction from either cohort would be more likely to undergo an autologous flap, or conversion to a delayed reconstruction. In terms of when to operate, and which operation to do, patients in the RTU ADM group may have benefited from judgement informed by a greater experience than that afforded the FD ADM group.

The results of this study have several implications for clinical practice. For immediate implant-based breast reconstruction with an ADM, a shorter rehydration time coupled with our findings of an equivalent, if not favorable complication profile with regards to explantation rates, supports the use of RTU ADM. This is important because up to recently, some insurance companies considered RTU ADM to be experimental, arguing that there was

insufficient data to support its use, and would not reimburse hospitals for its use in breast reconstruction. In addition to clinicians and patients, these data are also relevant to hospital administrators and payer groups. As the US healthcare system shifts to value-based healthcare (minimizing cost while maximizing outcomes) and hospitals attempt to control supply costs in operations, it is important to have comparative studies for devices and products frequently used in routine procedures. In addition to Alloderm RTU ADM, there are several new ADM products now on the market for clinicians to utilize in implant-based breast reconstruction procedures. Evaluating these products with similar rigor to the more established ADM products is critical to ensure patient safety and maintain an evidence-based clinical practice. In addition to comparing two different types of ADM, this study also provides valuable data on risk factors for complications in immediate implant-based breast reconstruction with ADM, and identifies patients who may benefit from delayed reconstruction,(25, 26, 37) or autologous reconstruction.(41) We gave oral antibiotics while drains were in, but this approach is not supported by the Surgical Care Improvement Project which recommends stopping antibiotics within 24 hours of surgery.(42) These guidelines, however, assume that the breast is a clean surgical site, but it is not.(30–32, 43) A precision, evidence-based approach, that tailors the type and duration of antibiotic use to a patient's genome and microbiome represent next steps for limiting infections in tissue expander patients.(44, 45) Ultimately, breast reconstruction remains a preference-sensitive decision and a shared decision-making approach that, when optimized, considers patients' values and preferences and balances those against risks for adverse outcomes associated with different techniques.(46)

The primary limitation of this study is the retrospective, non-randomized study design. Ideally, a study with level one evidence could be performed to compare FD and RTU ADM; however, conducting a randomized-controlled trial with sufficient power to detect clinically meaningful differences in outcomes across the two groups is resource intensive and was not practical for this study. We acknowledge with a retrospective study design the presence of unknown confounders that may impact our results.

CONCLUSIONS

Immediate implant-based breast reconstruction with sterile, ready-to-use acellular dermal matrix was associated with fewer explantations but no difference in infection rates compared to reconstruction with aseptic, freeze-dried acellular dermal matrix. As technology and techniques evolve and ADM use becomes more prevalent in implant-based breast reconstruction, it is important that additional comparative studies are performed with adequate sample sizes and long-term follow-up to ensure patient safety and optimal clinical outcomes.

Acknowledgements:

The authors would like to thank Dr. Keith Brandt and Dr. Marissa Tenenbaum, who along with Dr. Myckatyn, contributed patients to this series. We are grateful to Acelyty for funding this study. We are also grateful to Ms. Colleen Kilbourne-Glynn for administrative support for this study and Ms. Annette Irving for assistance with institutional review board preparation.

Financial Disclosures: This study was funded by an investigator-initiated grant from LifeCell (PI: Myckatyn, Grant Number: IIT-2017-10024). TMM receives investigator-initiated grant funding, consultant, and advisory board fees from Allergan, consultant fees from LifeCell, investigator-initiated grant funding and consultant fees from RTI, and advisory board fees from Viveve. RPP received support from a National Institutes of Health (NIH) Institutional National Research Service Award (T32CA190194). The content is solely the responsibility of the authors and does not necessarily represent the official view of the NIH. None of the authors have any disclosures.

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Table 1.

Patient and clinical characteristics for aseptic, freeze-dried acellular dermal matrix versus sterile, ready-to-use acellular dermal matrix

Characteristic	FD ADM*	RTU ADM	<i>p</i> -value
Number of Patients	612	673	
Number of Breasts	910	1129	
Age, year	49.5 ± 10.2	49.6 ± 11.0	0.8646
Body Mass Index (BMI)	28.5 ± 6.3	28.1 ± 6.7	0.3198
Smoker	342 (55.8)	436 (64.8)	0.0011
- Never	146 (23.9)	135 (20.1)	0.0997
- Former	124 (20.3)	102 (15.2)	0.0163
- Current			
Diabetes	48 (7.8)	44 (6.5)	0.3647
History of Chest Wall Radiation	4 (0.7)	40 (5.9)	< 0.0001
Adjuvant Radiation	216 (35.3)	223 (33.1)	0.4151
Neoadjuvant Chemotherapy	183 (29.9)	152 (22.6)	< 0.0001
Adjuvant Chemotherapy	262 (42.8)	195 (28.9)	< 0.0001
Endocrine Therapy	213 (34.8)	265 (39.4)	0.0904
Cancer Stage	6 (0.9)	138 (20.5)	< 0.0001
- 0	210 (34.3)	206 (30.7)	0.1617
- 1	166 (27.1)	223 (33.0)	0.0212
- 2	230 (37.6)	106 (15.8)	< 0.0001
- 3			
Bilateral Reconstruction	298 (48.7)	456 (67.8)	< 0.0001
Bilateral Prophylactic Mastectomy	0 (0.0)	49 (7.3)	< 0.0001
Nipple-Sparing Mastectomy	9 (1.0)	242 (21.4)	< 0.0001
Tissue Expander Reconstruction	910 (100)	1023 (90.6)	< 0.0001
Direct to Implant Reconstruction	0 (0.0)	106 (9.4)	< 0.0001

* Data is reported as means with standard deviations for continuous variables and as number and percentiles for categorical variables. ADM, acellular dermal matrix; FD, freeze-dried; RTU, ready-to-use.

Table 2.

Patient level clinical outcomes for aseptic, freeze-dried acellular dermal matrix versus sterile, ready-to-use acellular dermal matrix.

Complication	FD ADM*	RTU ADM	p-value
Surgical Site Infection	69 (11.3)	70 (10.4)	0.6075
Explant	110 (18.0)	82 (12.2)	0.0036
Wound Dehiscence	15 (2.5)	6 (0.9)	0.3243
Mastectomy Flap Necrosis	15 (2.5)	5 (0.7)	0.1908
Implant Problem **	15 (2.5)	5 (0.7)	0.1908
Seroma	32 (5.2)	40 (6.0)	0.5735
Hematoma	7 (1.1)	13 (1.9)	0.2531

* Data is reported as number and percentile. ADM, acellular dermal matrix; FD, freeze-dried; RTU, ready-to-use.

** "Implant problem" is defined as implant exposure, malposition, deflation, or rupture.

Table 3.

Independent Predictors for Surgical Site Infections

Variable	Adjusted OR (95% CI)	p-value
Aseptic, Freeze-Dried ADM	1.064 (0.732 – 1.546)	0.7455
Diabetes	1.479 (0.807 – 2.710)	0.2053
Adjuvant Chemotherapy	1.238 (0.789 – 1.943)	0.0960
History of Chest Wall Radiation	1.180 (0.777 – 1.793)	0.4372
Adjuvant Radiation	1.899 (0.823 – 4.380)	0.1328
BMI	1.039 (1.012 – 1.066)	0.0037

* ADM, acellular dermal matrix; BMI, body-mass index; OR, odds ratio; CI, confidence interval

Table 4.

Independent Predictors for Prosthetic Explantation

Variable	Adjusted OR (95% CI)	<i>p</i> -value
Aseptic, Freeze-Dried ADM	1.570 (1.087 – 2.267)	0.0161
Current Smoker	2.809 (1.916 – 4.115)	0.0002
Diabetes	1.724 (0.986 – 3.012)	0.0559
Adjuvant Chemotherapy	1.318 (0.884 – 1.965)	0.0031
History of Chest Wall Radiation	1.360 (0.602 – 3.049)	0.8367
Adjuvant Radiation	2.040 (0.920 – 4.525)	0.0256
BMI	1.054 (1.030 – 1.079)	< 0.0001

* ADM, acellular dermal matrix; BMI, body-mass index; OR, odds ratio; CI, confidence interval

Table 5.

Independent Predictors for Any Complication

Variable	Adjusted OR (95% CI)	p-value
Aseptic, Freeze-Dried ADM	1.149 (0.843 – 1.568)	0.3794
Current Smoker	2.053 (1.458 – 2.899)	0.0047
Diabetes	1.495 (0.909 – 2.457)	0.1129
Adjuvant Chemotherapy	1.259 (0.887 – 1.788)	0.0103
History of Chest Wall Radiation	1.172 (0.574 – 2.404)	0.4272
Adjuvant Radiation	1.980 (1.016 – 3.984)	0.0059
Stage 1 Cancer	0.688 (0.403 – 1.175)	0.1712
Stage 2 Cancer	0.557 (0.311 – 1.001)	0.0502
Stage 3 Cancer	0.584 (0.305 – 1.115)	0.1029
BMI	1.047 (1.026 – 1.069)	< 0.0001

* ADM, acellular dermal matrix; BMI, body-mass index; OR, odds ratio; CI, confidence interval