Use of Acellular Dermal Matrix in Postmastectomy Breast Reconstruction: Are All Acellular Dermal Matrices Created Equal?

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Background: AlloDerm and FlexHD are two types of acellular dermal matrices commonly used in implant-based reconstruction. Although the use of acellular dermal matrix has revolutionized immediate breast reconstruction in the setting of breast cancer, it remains unclear which type of acellular dermal matrix is best. The purpose of this retrospective cohort study was to compare postoperative complication rates between these two types of acellular dermal matrix.
Methods: The authors reviewed the records of all patients who underwent implant-based breast reconstruction at their institution between 1998 and 2013. Dependent variables of seroma, hematoma, infection, delayed wound healing, implant exposure, and return to the operating room for management of complications were recorded.
Results: A total of 309 consecutive patients were identified. Of these, AlloDerm was used in 123 patients (39.8 percent) and FlexHD was used in 186 patients (60.2 percent). Most patients in the authors' cohort underwent immediate reconstruction [$n = 288$ (93.2 percent)], with a mean follow-up of 20.0 months. Patients receiving AlloDerm were half as likely to have major infections compared with patients receiving FlexHD (OR, 0.50; 95 percent CI, 0.16 to 1.00; $p < 0.05$). The rates of other complications were similar between the two groups.
Conclusion: There are significantly increased odds of a major infection in patients who undergo implant-based breast reconstruction using FlexHD compared with AlloDerm. (*Plast. Reconstr. Surg.* 136: 647, 2015.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

Tissue expander and implant-based methods of breast reconstruction continue to be the techniques most commonly used to restore form and function after mastectomy.[1] The use of acellular dermal matrix has revolutionized immediate breast reconstruction, increasing the rate of expansion, creating a predictable contour of the lower pole, and designing more aesthetically pleasing inframammary folds. However, the use of acellular dermal matrix incurs additional costs and may be associated with higher risks of complications compared with tissue expander placement alone.[2–11] Although numerous studies have described the benefits of matrix, including additional coverage over the implant beneath tenuous postmastectomy skin, others have warned against the use of matrix, noting higher rates of seromas, infections, explantations, and cost.[12–16] Overall, however, the potential benefits have outweighed the risks in the setting of immediate breast reconstruction, and acellular dermal matrix use is now commonplace.

With increasingly widespread use of acellular dermal matrix in breast reconstruction, several products are now being offered.[17–19] AlloDerm (LifeCell Corp., Branchburg, N.J.) and FlexHD (Ethicon, Inc., Somerville, N.J., and Musculoskeletal Transplant Foundation, Edison, N.J.) are two of the most commonly used forms of acellular dermal matrix on the market today.[20] Both products are composed of allogenic acellular tissue

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matrices of similar thickness (0.8 to 1.7 mm) created by removing immunogenic components from human cadaveric skin.[21] Several characteristics distinguish the various products. Although AlloDerm is packaged in two different forms (prehydrated and freeze-dried), FlexHD comes in only one prehydrated form.[22–26] Cost also varies between the two products, with FlexHD priced at approximately $500 less than AlloDerm at our institution. Over time, however, some insurance companies have arbitrarily selected which brand of acellular dermal matrix they will cover for use in breast reconstruction, leaving surgeons with limited choices and input in this process. The goal of the current study was to compare complication rates between FlexHD and AlloDerm in the setting of breast reconstruction, to assist providers, payers, and patients in making informed choices regarding the use of acellular dermal matrix in the setting of breast reconstruction.

PATIENTS AND METHODS

All adult patients who underwent implant-based breast reconstruction following mastectomy at a university center between January of 1998 and December of 2013 were enrolled in this retrospective study. Approval from the University of Michigan Institutional Review Board was obtained. Chart review was performed to obtain demographic data, comorbidities, oncologic management details, and specific surgical details on patients undergoing implant-based reconstructions using acellular dermal matrix. Reconstructions were performed by seven surgeons at our institution, and use of AlloDerm or FlexHD was based on surgeon preference. The primary outcomes of interest were complications, identified as seroma, hematoma, infection, delayed wound healing or mastectomy flap necrosis, implant exposure, and return to the operating room for management of a complication. An analysis of postoperative outcomes was performed by patient and by breast, as the units of analysis. Patients with greater than 30 days of follow-up were eligible for inclusion.

Criteria published by the Centers for Disease Control and Prevention were used to define the presence of infection in this study, as follows: (1) presence of purulent drainage; (2) positive aseptically obtained culture; (3) peri-incisional erythema and incision opened by the surgeon; or (4) physician diagnosis of infection, such as cellulitis, for which antibiotics were prescribed. We defined minor infections as those treated with oral antibiotics and major infections as those requiring treatment with intravenous antibiotics with or without surgical exploration.

Statistical Analysis

The data were analyzed by patient and by breast, assuming each breast was independent. Analysis by treating each breast as independent is more common in the related literature. However, this approach inflates the sample size and does not control for intrapatient similarity. We chose to include these results to allow comparison to previous studies in the literature. Patient characteristics and complication rates in cases using AlloDerm and FlexHD were compared using t tests or Wilcoxon rank sum tests for continuous variables, and chi-square tests or Fisher's exact tests for categorical variables. Logistic models were built based on known confounders of complication type, with the primary independent variable of interest being the type of acellular dermal matrix (AlloDerm versus FlexHD). A multinomial model was used to investigate the association of infection with patient characteristics. This is a logistic model with three levels—no infection, minor infection, and major infection—where we set no infection as the reference level and model the odds of minor infection versus no infection and the odds of major infection versus no infection. With each covariate in the model, the association between that characteristic and the odds of minor infection versus no infection is estimated by an odds ratio, 95 percent confidence interval, and corresponding p value. The same is estimated for the association of that variable and the odds of a major infection versus no infection. That variable also has an overall p value for its association to the odds of infection as a whole. Statistical significance was designated at the $p < 0.05$ level. All analysis was done with SAS 9.3 (SAS Institute, Inc., Cary, N.C.).

RESULTS

Summary of Demographic Data

Of the 309 patients include in our study, 212 underwent bilateral acellular dermal matrix reconstruction and 97 underwent unilateral matrix reconstruction. Two hundred eighty-eight women (93.2 percent) underwent immediate reconstruction, 13 (4.2 percent) underwent delayed reconstruction, and eight (2.6 percent) underwent bilateral reconstruction using both an immediate reconstructive procedure on one

Table 1. Patient Demographics for Total Cohort and by Acellular Dermal Matrix Type

Variable	Total (%)	AlloDerm (%)	FlexHD (%)	*p*
No. of patients	309	123	186	
No. of breasts	521	206	315	
Mean age ± SD, yr	47.3 ± 9.5	47.4 ± 9.9	47.2 ± 9.3	0.81
Mean BMI ± SD, kg/m²†	26.4 ± 5.7	26.5± 5.6	26.3 ± 5.7	0.67
Mean follow-up ± SD, yr	1.7 ± 1.3	2.0 ± 1.7	1.4 ± 0.9	0.007*
Mean initial TE fill/implant volume ± SD, ml†‡	146.5 ± 105.6	152.1 ± 107.2	142.3 ± 104.4	0.19
Smoking	19 (6.1)	11 (8.9)	8 (4.3)	0.10
Radiation therapy	15 (4.9)	8 (6.5)	7 (3.8)	0.27
Chemotherapy	35 (11.3)	19 (15.4)	16 (8.6)	0.06
Hypertension	41 (13.3)	17 (13.8)	24 (12.9)	0.82
Diabetes	10 (3.2)	5 (4.1)	5 (2.7)	0.50
Previous malignancy	12 (3.9)	8 (6.5)	4 (2.2)	0.07
Oncologic indication for mastectomy‡	251 (48.2)	104 (50.5)	147 (46.7)	0.39
Use of antibiotic irrigation†‡	482 (95.8)	191 (95.0)	291 (96.0)	0.75

BMI, body mass index; TE, tissue expander.
*Statistically significant ($p < 0.05$). The χ^2 test of independence or Fisher's exact test was used to obtain p values for categorical variables. The t test was used for age, and the Wilcoxon rank sum test was used for body mass index and years of follow-up.
†Indicates missing: BMI missing for one patient; TE fill missing or not applicable for 75 breasts; antibiotic irrigation missing for 17 patients.
‡By breast, not by patient.

side and a delayed procedure on the contralateral side. The most common indication for mastectomy was a current diagnosis of breast cancer, with only 41 of 309 patients (13.3 percent) undergoing mastectomy for prophylaxis. The mean age of the women was 47.3 ± 9.5 years. Additional demographic details are listed in Table 1.

A total of 521 breasts were reconstructed using acellular dermal matrix. AlloDerm was used in 206 breasts (123 patients) and FlexHD was used in 315 breasts (186 patients). Although mean length of follow-up for patients with AlloDerm was 7 months longer than for patients with FlexHD (mean, 2.0 ± 1.7 years versus 1.4 ± 0.9 years, respectively; $p = 0.007$), there were no other significant differences in patient-specific demographic variables between patients who underwent AlloDerm- and FlexHD-based reconstructions (Table 1). Follow-up was defined by the time since initial tissue expander placement or one-stage implant reconstruction. This difference was controlled for in our multivariable analysis.

Expander/Implant Complications

All complications are reported according to individual patient data unless stated otherwise. Across both groups, the most common complication was return to the operating room, which occurred in 20.4 percent of patients. Fifty-six patients (18.1 percent) developed a major or minor infection and required antibiotic therapy with or without surgical exploration (Table 2). A total of 11 expanders and implants among 28 surgical-site infection cases were removed for major infection, resulting in an antibiotic salvage rate of 60.7 percent. Of the devices explanted, five were expanders and six were permanent implants. In our data set, there were no minor infections that resulted in removal of an expander or permanent implant. Fifteen patients (4.9 percent) were diagnosed with a seroma during their postoperative course. A summary of complications is reported in Table 2.

Table 2. Summary of Complications

	By Patient (%)	By Breast (%)
No.	309	521
Outcome		
Seroma	15 (4.9)	18 (3.5)
Hematoma	18 (5.8)	19 (3.6)
Surgical-site infection		
None	253 (81.9)	455 (87.3)
Minor	13 (4.2)	15 (2.9)
Major	43 (13.9)	51 (9.8)
Delayed wound healing	14 (4.5)	18 (3.5)
Return to OR	63 (20.4)	73 (14.0)
Implant exposure	7 (2.3)	7 (1.3)

OR, operating room.

AlloDerm versus FlexHD

There was a significantly higher rate of major (17.7 percent versus 8.1 percent) and minor (4.8 percent versus 3.8 percent) infections in the patients who received FlexHD compared with those who received AlloDerm ($p = 0.039$) (Table 3). No significant differences in rates of seroma, hematoma, delayed wound healing, return to the operating room, or implant exposure were identified through univariable analyses.

Results of the multivariable analyses are summarized in Table 4 using individual patient data and in Table 5 using individual breast data.

Table 3. Postoperative Complications between the Use of AlloDerm versus FlexHD

Outcome	By Patient (n = 309)			By Breast (n = 521)		
	AlloDerm (%)	FlexHD (%)	p	AlloDerm (%)	FlexHD (%)	p
No.	123	186		206	315	
Outcome						
Seroma	8 (6.5)	7 (3.8)	0.27	9 (4.4)	9 (2.9)	0.36
Hematoma	8 (6.5)	10 (5.4)	0.68	9 (4.4)	10 (3.2)	0.48
Surgical-site infection						
None	109 (88.6)	144 (77.4)		191 (92.7)	264 (83.8)	
Minor (oral antibiotics)	4 (3.8)	9 (4.8)		4 (1.9)	11 (3.5)	
Major (IV antibiotics)	10 (8.1)	33 (17.7)	0.039*	11 (5.3)	40 (12.7)	0.011*
Delayed wound healing	4 (3.3)	10 (5.4)	0.38	5 (2.4)	13 (4.1)	0.30
Return to OR	25 (20.3)	38 (20.4)	0.98	28 (13.6)	45 (14.3)	0.82
Implant exposure	3 (2.4)	4 (2.2)	1.0	3 (1.5)	4 (1.3)	0.86

IV, intravenous; OR, operating room.
*Statistically significant ($p < 0.05$). The χ^2 test of independence or Fisher's exact test was used to obtain p values.

As stated previously, analysis by assuming that each breast is an independent subject artificially inflates sample size and does not control for intrapatient similarity. However, we performed analyses using both individual breast and patient data to allow comparisons with similar studies in the literature. On controlling for potential confounding factors in our multivariable analysis, there was a significantly higher risk of major infection with increased body mass index (OR, 1.07; 95 percent CI, 1.01 to 1.13; $p = 0.035$) and with use of FlexHD (OR, 0.50; 95 percent CI, 0.16 to 1.00; $p = 0.049$). There were no significant differences in the rates of hematoma, seroma, or delayed wound healing (Tables 4 and 5).

Table 4. Results from Multiple Regression Models Comparing the Use of AlloDerm versus FlexHD, by Patients

Outcome and Predictors	OR (95% CI)	p
Seroma (n = 309)		
Age	1.01 (0.94–1.08)	0.77
Years' follow-up	1.72 (1.18–2.52)	0.005*
Bilateral vs. unilateral	3.68 (0.35–38.83)	0.28
Initial fill volume/100 ml	1.66 (0.96–2.87)	0.07
AlloDerm vs. FlexHD	1.24 (0.28–5.48)	0.77
Delayed healing/necrosis (n = 309)		
Age	1.00 (0.93–1.07)	0.95
Years' follow-up	0.96 (0.55–1.68)	0.87
Smoker (current vs. former/never)	4.33 (0.79–23.88)	0.09
Radiation therapy	2.16 (0.24–19.75)	0.50
Bilateral vs. unilateral	2.64 (0.32–21.58)	0.37
AlloDerm vs. FlexHD	0.53 (0.13–2.17)	0.38
Infection (n = 308)†		
Age		0.45
Minor vs. none	1.04 (0.98–1.11)	0.21
Major vs. none	1.00 (0.96–1.04)	0.92
Years' follow-up		0.80
Minor vs. none	0.84 (0.45–1.57)	0.59
Major vs. none	1.06 (0.78–1.47)	0.71
BMI		0.11
Minor vs. none	1.02 (0.91–1.13)	0.78
Major vs. none	1.07 (1.01–1.13)	0.035*
AlloDerm vs. FlexHD		0.13
Minor vs. none	0.64 (0.16–2.69)	0.53
Major vs. none	0.50 (0.16–1.00)	0.049*

BMI, body mass index.
*Statistically significant ($p < 0.05$).
†Multinomial regression of the odds of minor infection and major infection vs. no infection. For each covariate, there is an odds ratio and corresponding p value for the comparison of minor infection vs. none and major infection vs. none, respectively, and overall p value for the significance of that variable in the entire model aligned with the covariate name.

DISCUSSION

The use of acellular dermal matrix in immediate breast reconstruction following mastectomy has become commonplace, with advantages including greater initial tissue expander fill volume, minimization of local tissue trauma, and improved support of the implant against the traumatized mastectomy skin. Although many studies have demonstrated increased complication rates associated with the use of acellular dermal matrix compared with complete submuscular coverage, the benefits and widespread use of matrix have prompted a proliferation of manufacturers for this product. Choosing the "right" acellular dermal matrix depends on the relative benefits, risks, and costs of the various brands. To date, few studies have evaluated outcomes across these products. Liu et al. recently published a study documenting no differences in complication rates between AlloDerm and FlexHD across 262 patients, but noted a trend toward increased rates of infection with use of FlexHD that was not statistically significant.[21] Importantly, although the report by Liu et al. suggests that the use of FlexHD may be an independent risk factor for implant loss, the authors acknowledge that the small sample size, retrospective design of the study, and use of individual breasts (rather than patients) as the

Table 5. Results from Multiple Regression Models Comparing the Use of AlloDerm versus FlexHD, by Breasts

Outcome and Predictors	OR (95% CI)	*p*
Seroma (*n* = 521)		
Age	1.01 (0.95–1.06)	0.81
Years' follow-up	1.88 (1.36–2.59)	0.0001*
Initial fill volume/100 ml	1.37 (0.90–2.11)	0.15
AlloDerm vs. FlexHD	0.63 (0.20–2.02)	0.44
Delayed healing/necrosis (*n* = 521)		
Age	0.99 (0.94–1.04)	0.65
Years follow-up	0.99 (0.65–1.51)	0.97
Smoker (current vs. former/never)	3.68 (0.95–14.33)	0.06
Radiation therapy	1.83 (0.39–8.49)	0.44
AlloDerm vs. FlexHD	0.51 (0.17–1.52)	0.23
Infection (*n* = 520)†		
Age		0.42
Minor vs. none	1.04 (0.98–1.10)	0.19
Major vs. none	1.00 (0.97–1.03)	0.90
Years' follow-up		0.45
Minor vs. none	1.22 (0.81–1.84)	0.35
Major vs. none	1.12 (0.88–1.44)	0.36
BMI		0.25
Minor vs. none	1.02 (0.94–1.12)	0.62
Major vs. none	1.04 (0.99–1.09)	0.10
AlloDerm vs. FlexHD		0.007*
Minor vs. none	0.43 (0.12–1.46)	0.17
Major vs. none	0.35 (0.17–0.71)	0.004*

BMI, body mass index.
*Statistically significant ($p < 0.05$).
†Multinomial regression of the odds of minor infection and major infection versus no infection. For each covariate, there is an odds ratio and corresponding *p* value for the comparison of minor infection vs. none and major infection vs. none, respectively, and overall *p* value for the significance of that variable in the entire model aligned with the covariate name.

units of analysis significantly limit their ability to draw definitive conclusions. In our cohort, there were 309 women (521 breasts) who underwent reconstruction with acellular dermal matrix, and we present results according to both breast and patient-specific data. We focus on patient-specific methods of statistical analysis, however, as each breast on a woman is not actually independent. For each woman, the two breasts are correlated such that what occurs to one is more likely to occur to the other; using standard statistical tests assuming independence, such as linear regression, leads to inflated sample size, deflated variance, biased results, and *p* values that are smaller than they should be, often concluding statistical significance when this is not the case.

In this study, we compared outcomes between 123 patients who received AlloDerm and 186 patients who received FlexHD for breast reconstruction and found a statistically increased risk of major and minor infection with use of FlexHD compared with AlloDerm. No differences in rates of seroma, hematoma, wound healing, return to the operating room, or implant exposure were noted, as is to be expected given the similarities in function between AlloDerm and FlexHD with regard to development of these particular complications. Although only 10 patients (8.1 percent) developed major infections with use of AlloDerm, more than twice the proportion of patients developed major infections after use of FlexHD (17.7 percent). Although the reason behind this difference remains unclear, one potential explanation may be differences in preparation and processing of these two materials; assessing the exact differences in processing, however, is not currently possible, given the proprietary nature of the techniques used to aseptically prepare these two products. Importantly, neither product is terminally sterilized. In vitro studies have demonstrated higher monocyte and macrophage activation, resulting in an increase in interleukin-1β with the use of FlexHD versus AlloDerm.[27] As a result, there may be more inflammation associated with the use of FlexHD. Randomized studies comparing acellular dermal matrices with different techniques of production are needed to better explain this finding.

Our findings have serious implications for implant-based breast reconstruction. As stated previously, insurance companies have seemingly arbitrarily decided to cover one type of acellular dermal matrix over another, resulting in limited choices for surgeons and patients considering matrix options. In this study, however, we present objective data from a large cohort demonstrating a significantly increased rate of infections in patients who underwent reconstruction using FlexHD compared to AlloDerm. Patients who received FlexHD were twice as likely to develop an infection as similar patients who received AlloDerm. In the setting of immediate breast reconstruction, infection can significantly compromise the reconstruction, requiring inpatient hospitalization, long-term intravenous antibiotics, and implant loss. Thus, identifying all potential factors that can increase the risk of infection is important. In addition to counseling patients with elevated body mass index (a known risk factor based on previous literature), regarding the increased risk for complications, we should now also consider discussing potential complications associated with choice of acellular dermal matrices.

Our study has some limitations. Although this analysis used one of the largest sample sizes in the current literature to assess outcomes in breast

reconstruction with regard to brand differences in acellular dermal matrix, the impact and generalizability of our findings would be enhanced by the use of an even larger sample size and multicenter data. In addition, we were unable to control for variations in preparation of FlexHD and AlloDerm over time given the proprietary nature of this information.[22] In the future, meta-analyses and randomized trials will be important for definitively evaluating differences in complication rates between various preparations of acellular dermal matrix in breast reconstruction. Although we did not control for individual surgeon factors in our analysis, our findings are more generalizable as presented, given national variations in surgeon practice patterns and techniques.

CONCLUSIONS

The use of acellular dermal matrix in breast reconstruction has broadened the applications of implant-based reconstruction in the setting of breast cancer. In this study, we determine that there is a significantly increased risk of infection associated with the use of FlexHD compared with AlloDerm. The delineation of the impact of such complications has the potential to affect economic policies for hospitals and insurance companies, surgeon preferences, and patient satisfaction after breast reconstruction.

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