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Orion P. Keifer, *Emory University*
Eugenia K. Page, *Emory University*
Alexandra Hart, *Emory University*
Randall Rudderman, *Emory University*
Grant Carlson, *Emory University*
Albert Losken, *Emory University*

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ORIGINAL ARTICLE

Breast

A Complication Analysis of 2 Acellular Dermal Matrices in Prosthetic-based Breast Reconstruction

Orion P. Keifer, Jr, MD, PhD,*
Eugenia K. Page, MD,*
Alexandra Hart, MD,†
Randall Rudderman, MD, FACS,†
Grant W. Carlson, MD,*
Albert Losken, MD, FACS*

Background: Acellular dermal matrices (ADM) are now routine in postmastectomy prosthetic-based breast reconstruction. The goal of the current study was to compare the complications of 2 ADM products—AlloDerm and Cortiva.

Methods: A retrospective analysis of prosthetic-based breast reconstruction in Atlanta, Ga., over 5 years. Inclusion criteria were the use of the ADM types (AlloDerm or Cortiva) and use of a tissue expander or implant. Statistical analysis compared group demographics, risk factors, and early complications.

Results: Of the 298 breast reconstructions, 174 (58.4%) used AlloDerm and 124 (41.6%) used Cortiva. There was no difference in overall complication frequency (16 AlloDerm and 18 Cortiva; $P = 0.195$). Within specific categories, there was a difference in mastectomy skin flap necrosis, but, based on further regression analysis, this was attributable to differences in body mass index ($P = 0.036$). Furthermore, there were no differences in the rates of infection (6 AlloDerm and 5 Cortiva; $P = 1.0$), seroma/hematoma (9 AlloDerm and 7 Cortiva; $P = 1.0$), or drain duration (13.2 day AlloDerm and 14.2 day Cortiva, $P = 0.2$). By using a general estimating equation for binomial logistical regression, it was found that only current tobacco use ($P = 0.033$) was a significant predictor for a complication. Trending predictors were body mass index ($P = 0.074$) and age ($P = 0.093$). The type of matrix was not a significant predictor for any of the recorded complication ($P = 0.160$).

Conclusions: Although AlloDerm is well established, we have shown that Cortiva has an equivalent complication frequency. Future work will focus on long-term outcome measures and histological evaluation of vascularization and integration.

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Breast cancer is one of the leading malignancies in women.[1] Despite advances in chemotherapy, hormone therapy, and radiotherapy, curative treatment for breast cancer requires surgical intervention, often in the form of a mastectomy.[2,3] As the loss of breasts has deleterious effects both on patients' psyche and their long-term outcomes, breast reconstruction has become standard of care post mastectomy.[4–6] There are numerous options for breast reconstruction including the timing (immediate versus delayed), extent of resection (nipple/skin sparing, simple, and modified radical), and mass of reconstructed breast mound (autologous—TRAM, DIEP, GAP LDM flap, and prosthetics—tissue expander/implant). Given the innumerable combinations of these options, several studies have attempted to compare different methods. Currently, there is evidence that an immediate reconstruction may be superior to delayed reconstruction.[2] Furthermore, there is evidence that nipple- and skin-sparing mastectomies are sufficient as a curative treatment and superior for cosmesis.[7] Therefore, in the context of a growing trend of immediate reconstruction after nipple- and skin-sparing mastectomies, it is not surprising that the use of tissue expander–based and implant-based reconstruction accounts for over 80% of the 102,215 breast reconstructions reported by the American Society of Plastic Surgeons for 2014.[8] For these tissue expander–based and implant-based reconstructions, there is another growing trend—the use of an acellular dermal matrix (ADM) as an integral component of the surgery.[9–11]

*From the *Division of Plastic and Reconstructive Surgery, Emory University School of Medicine, Atlanta, Ga.; and †Private Practice, Atlanta, Ga.*

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The ADM was introduced in the mid-1990s for burn reconstruction, but its use has expanded to include many applications.[12] In particular, in the mid-2000s, several reports were published showing the benefits of using ADM in implant-based and tissue expander–based reconstruction.[13–18] Since that time, the use of ADM in these procedures has grown tremendously. Several advantages of using an ADM have been reported. These include claims of superior benefits in terms of cosmetic outcomes secondary to greater control of the inframammary fold position (ie, more support, less visible implant rippling, and more fullness of lower pole), lower incidence of capsular contracture, higher initial volumes of implants and tissue expanders with shorter time to full expansion, and less tension on mastectomy skin flaps.[19–22] However, only some of these benefits have been formally evaluated.[23]

Given the increased use of ADMs, several companies have introduced their own versions of ADM that vary in a number of properties including harvesting source, crosslinking management, and the process for removing antigens. With the advent of these newer ADMs, there is a need to compare these different matrices in terms of complication frequency and type. Here, we add to this growing and necessary literature by comparing 2 human ADMs: the AlloDerm regenerative tissue matrix (RTM, LifeCell Corporation, Bridgewater, N.J.) and Cortiva allograft dermis (RTI Surgical, Alachua, Fla.). Although the characteristics of the AlloDerm RTM are documented elsewhere,[24] Cortiva is an 8- x 16-cm Tutoplast-sterilized, noncrosslinked allograft dermis (Fig. 1).

PATIENTS AND METHODS

All patients undergoing either implant-based or tissue expander–based breast reconstruction at Emory University and a private practice between April 2010 and August 2015 were included in this retrospective analysis. Approval from the Emory University Institutional Review Board was obtained to conduct the study. Inclusion criteria included the following: the use of 1 of the 2 types of ADM (AlloDerm RTM or Cortiva), at least 60 days of documented follow-up postoperatively, and sufficient data available from chart review. Review of the electronic medical record was conducted to collect patient data on demographics, amedical and surgical history, breast reconstruction surgical details, oncological diagnosis and management, and follow-up course. All mastectomy types were included. A total of 3 surgeons performed the breast reconstructions: 2 surgeons based at Emory University (A.L. and G.W.C.) and 1 surgeon in private practice (R. R.). The primary outcome of interest was the incidence of postoperative complications. Complications were further categorized as seroma (requiring clinic or operating room aspiration/drainage), hematoma (requiring drainage in the operating room), infection (requiring PO or intravenous antibiotics), and mastectomy skin flap necrosis (requiring debridement or serial dressing changes) to look at the distribution of these complications.

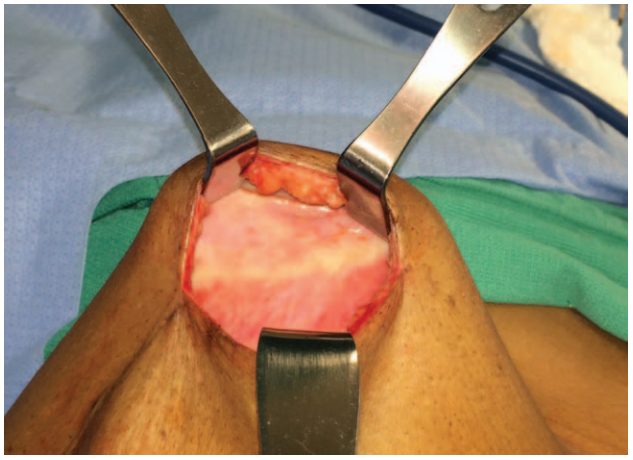

Fig. 1. Cortiva ADM integration. Image of the Cortiva ADM integration in a patient undergoing tissue expander to implant exchange.

Statistical Analysis

The vast majority of the cases included were bilateral reconstructions (81.9%); thus, there was concern that these breasts were not independent. Therefore, when possible, the analyses were adjusted for clustering to correct for any potential dependence between breast pairs. All continuous data were reviewed for potential outliers, which were defined as values >3 SDs from the mean (11 breasts from 9 patients were excluded). Any cases with outliers were removed from analysis. The resulting patient characteristics, demographics, and complication frequencies between the 2 matrix types were compared using Fisher exact test (categorical variables), *t* tests, and Mann–Whitney *U* test (continuous variables, normally or not-normally distributed, respectively). Additionally, a binomial logistic regression model using a general estimating equation (GEE) approach was used to determine significant predictors of whether a complication would occur or not. In addition to the matrix type, other a priori predictors were based on published data and included age,[25,26] body mass index (BMI),[27,28] duration of drain in place,[29] preoperative radiation treatment,[20,27] hypertensive status,[25] and active smoking status.[20,27] In all cases, significance was defined as $P < 0.05$. Furthermore, the results from the regression models are presented in terms of odds ratio, 95% confidence interval (CI), and the respective *P* value. All analyses were conducted using SPSS statistics 22 (IBM, Armonk, N.Y.).

RESULTS

Summary of Demographic, Medical, and Surgical Data

Of the 166 patients in the current study, 136 (81.9%) patients had bilateral mastectomies and 30 (18.1%) had unilateral mastectomies, with a total of 298 breast reconstructions. Of these reconstructions, 100 (33.6%) were direct-to-implant reconstructions and 198 (66.4%) were tissue expander–based reconstructions. With respect to the ADM type, 174 (58.4%) used AlloDerm during the reconstruction and 124 (41.6%) used Cortiva.

When comparing the patient populations in the 2 different ADM groups (Table 1), it is notable that there were

a few significant differences between the groups. In particular, the Cortiva group was, on average, 1.6 years older, weighed nearly 1.7 kg more (thus had a higher BMI), was more likely to have hypertension and was more likely to have a cancer pathology diagnosis (mastectomy tissue). Importantly, all data presented are uncorrected, with a significance value of $P < 0.05$, as the comparisons were both planned and directed toward a single question of whether these groups are different. Alternatively, and more conservatively, a Bonferroni correction approach for multiple comparisons resulted in a significance threshold of 0.0024; thus, only age and the weight (and hence BMI) would be significantly different between the groups. However, all significant factors were controlled for in the binary logistic regression using the GEE approach (Table 3).

Complication Frequency with AlloDerm and Cortiva

Overall, there were a total of 34 (11.4%) complications in the series (Table 2). Of the 34 complications, 16 (9%) were in the AlloDerm group and 18 (14%) were in the Cortiva group, with no significant differences between the groups ($P = 0.195$). Further categorization of the types of complication showed that the Cortiva group was associated with significantly higher incidence of mastectomy flap necrosis (6 vs 1; $P = 0.022$). There were no significant differences in the frequency of infection or hematoma/seroma. Furthermore, there was no difference in the number of patients having to return to the operating room to resolve the complication (9 vs 13; $P = 0.115$).

Given the potential meaningful differences between groups (Table 1), a binary logistic regression model was built using a GEE approach. The primary outcome of the model was the occurrence of a complication, and the predictors used in the model are presented in Table 3. Of all the predictors, only the current smoking status of the patient was significant in predicting a complication. In particular, current smoking status was associated with an odds ratio of 5.262, with a 95% CI of 1.145–24.184 ($P = 0.033$). None of the factors that were different between the groups significantly predicted the occurrence of a complication nor did the type of ADM used in the surgery.

As there seemed to be a significant difference in the occurrence of mastectomy flap necrosis between the groups, this was further examined with another GEE logistic regression model looking at predictors of mastectomy flap necrosis from factors that were significantly different between the groups (age, BMI, cancer diagnosis, and hypertension) and the significant predictor from the overarching regres-

Table 1. Patient Demographics, Medical History, and Surgical Details for Each Matrix

Variable	Total (%)	AlloDerm (%)	Cortiva (%)	*P*
Patient count	166	98 (59)	68 (41)	
Breast count	298	174 (58.4)	124 (41.6)	
Mean age ± SD (y)	50.1 ± 10.9	48.5 ± 11.0	52.4 ± 10.3	**0.002***
Mean weight ± SD (kg)	64.8 ± 11.7	63.1 ± 11.0	69 ± 14.7	**0.008†**
Mean height ± SD (cm)	164.3 ± 6.6	164.2 ± 7.3	164.5 ± 5.5	0.921†
BMI ± SD	24.0 ± 4.3	23.4 ± 4.1	24.8 ± 5.5	**0.010†**
Hypertension	62 (20.8)	28 (45.2)	34(54.8)	**0.021‡**
Diabetes	20 (6.7)	11 (55)	9(45)	0.816‡
Smoking	12 (4)	6 (50)	6 (50)	0.564‡
Cancer diagnosis (mastectomy tissue)	136 (45.6)	88 (64.7)	48 (35.3)	**0.044‡**
Implant-based reconstruction	100 (33.6)	57 (57)	43 (43)	0.804‡
Expander-based reconstruction	198 (66.4)	117 (59.1)	81 (49.9)	
Mean initial implant/TE volume ± SD (mL)	323.5 ± 124.8	323.4 ± 137.9	323.7 ± 104.4	0.332†
Bilateral reconstruction	268 (89.9)	153(57.1)	115 (42.9)	0.241‡
Axillary lymph node dissection	64 (21.5)	40 (62.5)	24 (37.5)	0.478‡
Sentinel lymph node biopsy	135(45.3)	81 (60)	54 (40)	0.638‡
Preoperative radiation	7 (2.4)	5 (71.4)	2 (28.6)	0.703‡
Mean postoperative drain duration ± SD (d)	13.6 ± 6.7	13.2 ± 6.9	14.2 ± 6.4	0.200*
Surgeon 1	72 (24.2)	36 (50)	36 (50)	0.194‡
Surgeon 2	92 (30.8)	59 (64.1)	33 (35.9)	
Surgeon 3	134 (45)	79 (59)	55 (41)	
Nipple sparing	56 (18.2)	23 (40.7)	33 (59.3)	0.098‡
Skin sparing	242 (80.2)	150 (62.3)	92 (37.7)	

*Independent samples *t* test.
†Mann–Whitney *U* test.
‡Fisher exact test.
Bold value indicates a significant result.

Table 2. Patient Early Complications (<60 d) for Each Matrix

Variable	Total (%)	AlloDerm (%)	Cortiva (%)	*P*
Complication	34 (11.4)	16 (47)	18 (53)	0.195*
Seroma/hematoma	16 (5.4)	9 (56.3)	7 (43.7)	1.000*
Infection	11 (3.7)	6 (54.6)	5 (45.4)	1.000*
Mastectomy flap necrosis	7 (2.3)	1 (14.3)	6 (85.7)	**0.022***
Complication leading to reoperation	22 (7.3)	9 (40.9)	13 (59.1)	0.115*

*Fisher exact test
Bold value indicates significant result.

Table 3. Results from GEE Binomial Logistical Regression for Overall Complications

Predictors	Odds Ratio	95% CI	*P*
Age	0.969	0.934–1.005	0.093
BMI	1.116	0.989–1.259	0.074
Drain duration	0.970	0.919–1.025	0.277
Tobacco	5.262	1.145–24.184	**0.033**
Preoperative radiation	1.970	0.157–24.684	0.599
Matrix type	1.822	0.789–4.206	0.160
Cancer (mastectomy tissue)	1.696	0.846–3.397	0.136
Initial TE or implant volume	0.998	0.994–1.003	0.488
Tissue expander or implant reconstruction	0.582	0.171–1.976	0.385
Hypertension	1.184	0.375–3.732	0.773
Diabetes mellitus	1.049	0.159–6.936	0.960

Table 4. Results from GEE Binomial Logistical Regression of Skin Necrosis

Predictors	Odds Ratio	95% CI	*P*
Age	0.988	0.936–1.042	0.650
BMI	1.587	1.029–2.447	**0.036**
Tobacco	4.376	0.313–61.231	0.273
Matrix type	11.247	0.916–138.130	0.059
Cancer (mastectomy tissue)	0.625	0.141–2.774	0.536
Hypertension	1.130	0.202–8.646	0.772

sion (eg, smoking status). The results of the regression analysis (Table 4) suggest that the only significant predictor of mastectomy flap necrosis is BMI with an odds ratio of 1.587 and a 95% CI of 1.029–2.447 ($P = 0.036$). Notably, matrix type was not a significant predictor.

DISCUSSION

Given both the increase in the number of ADM options and the utilization of ADMs in breast reconstruction, it is necessary to study their complication frequency and types. There are a number of studies that have compared the variety of ADMs available. In that same vein, this study compared the commonly used AlloDerm matrix with the more recent Cortiva matrix. Importantly, this is the first study to evaluate the complications associated with Cortiva.

Our study consisted of 298 breast reconstructions, one of the largest data sets in the published literature. Of these breast reconstructions, approximately 58% used AlloDerm and 42% used Cortiva, which ensured an adequate number of cases for a balanced statistical analysis. The overall complication frequency across both ADMs was 11.4%, which is in line with the reported "true" complication rate of 12% based on a meta-analysis of previous ADM studies.[19] The overall demographic profiles were also in line with previous studies, suggesting generalizability to the population undergoing breast reconstruction.

With respect to the primary outcome measure, the results of the study show that there is no significant difference in the overall complication rates between AlloDerm and Cortiva. Furthermore, using regression analysis, it was found that the only significant predictor for a complication was current smoking status. The finding that smoking is associated with higher complications is well documented across the surgical literature, including numerous studies in breast reconstruction.[25,30,31] While not reaching significance, it is worth noting that age and BMI were trending toward significance ($P < 0.10$). These findings are also consistent with previous literature that has suggested, after smoking, BMI and age tend to be the next strongest predictors of complications.[25,27,28] Although there are multiple factors that resulted in a lack of significance, 1 major factor is that outpatients' mean BMIs were lower than those reported in other studies and had a smaller SD. Such differences are important as most studies report increased complications with BMI scores >30, which was about 10% of our sample.[32] Likewise, the relationship between age and complications is often associated with patients whose age is >65 years, which was about 8% of our sample.

Interestingly, although there were no differences in the overall complication rate, the frequency of mastectomy skin flap necrosis was significantly higher in the Cortiva group. However, given the number of factors that were different between the groups at baseline (eg, age, BMI, cancer diagnosis, and hypertension diagnosis), these factors along with ADM type and active smoking status were selected for regression analysis of only mastectomy skin flap necrosis. Based on the results of this analysis, BMI was the only significant predictor of mastectomy skin flap necrosis. Thus, after controlling for differences between groups, the type of matrix was not significant in predicting mastectomy skin flap necrosis. These findings are consistent with the fact that the Cortiva group had a significantly higher BMI when compared with the AlloDerm group (Table 1), and that BMI is a known predictor of mastectomy skin flap necrosis.[32]

In terms of limitations and generalization, there are number of items that should be mentioned. Overall, although the sample size is quite large compared with other published studies, the number of complications for analysis limits the robustness of the conclusions. These limitations were partially ameliorating statistical methods that could analyze the data at the breast level (versus the patient level) while accommodating for potential dependence between the pair of breasts. Additionally, although there are 2 centers from which patients' data were collected, these centers were located in the same town and may reflect regional demographic differences. Furthermore, the data are retrospective, hence neither blinded nor randomized, introducing potential confounders. Also, the follow-up complications were limited to the first 60 days, as longer term data are still not available for many patients. Thus, data were unable to address longer term complications including capsular contracture. Future work should involve a larger sample size, data from geographically separated multicenters, and longer follow-up duration for more long-term complications (eg, capsular contractures). Additionally, given the potential differences in complication type between matrices, additional histological analysis of integration and vascularization would be beneficial.

Orion Paul Keifer, Jr, MD, PhD
Emory University School of Medicine
c/o Emory MD/PhD Program
1648 Pierce Dr NE
Atlanta, GA 30307
E-mail: okeifer@emory.edu

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