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ORIGINAL ARTICLE BREAST SURGERY

Clinical Outcomes in Breast Reconstruction Patients Using a Sterile Acellular Dermal Matrix Allograft

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Abstract
Background Human acellular dermal matrices (ADMs) have enabled successful breast reconstructions while decreasing muscle donor morbidity and pain for the patient. However, some literature reports indicate an increase in complications, especially infection. The decellularization and terminal sterilization properties of DermACELL (D-ADM), a human ADM, may reduce the rate of complications in augmented breast reconstruction while still maintaining successful outcomes. In the study presented here, we evaluate the quality and safety of outcomes with the use of D-ADM during tissue expander breast reconstruction.
Methods A retrospective chart review was conducted of patients who underwent breast reconstruction with the use of D-ADM, at a single-military hospital-based practice, resulting in a population of 38 subjects and 58 breasts who had breast reconstruction augmented with D-ADM.
Results Fifty-six breasts (96.6%) in thirty-six patients demonstrated successful outcomes with a median 27 weeks' time to complete healing. Post-reconstruction radiation and chemotherapy were applied to 24.1 and 25.9% of reconstructions, respectively. Complications rates were minimal with rates of 1.7% for surgical site infection and 1.7% for red breast syndrome.
Conclusion The low complication rates combined with the high success and patient satisfaction rates observed for D-ADM support the use of this ADM in breast reconstruction.
Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these evidence-based medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Breast reconstruction · Acellular dermal matrix · DermACELL · Tissue expander

Introduction

Human acellular dermal matrices (ADMs) have been used with increased frequency over the last decade to assist during prosthetic breast reconstruction [1–4]. The benefits in utilizing these ADMs in this type of reconstruction are well documented in the literature [5–7]. These benefits include total mammary prosthetic coverage with a combination of ADM and the patient native muscle, larger volume of initial expansion, and decreased displacement of the prosthetic from the intended site of reconstruction. This technique has mainly replaced total muscle coverage by sparing the serratus anterior muscle which is usually small, thin and lacks enough area of coverage. Furthermore, this technique decreases muscle donor morbidity, resulting in reduced pain for the patient undergoing an already difficult surgery.

However, some studies have noted an increased risk of overall complications, especially infections, associated with the use of certain ADMs [5, 7]. The complication rates associated with the use of ADMs appear to widely vary dependent on the study, surgical technique and preparing process; therefore, ADMs cannot be taken as interchangeable. Several different aseptically processed and non-sterile ADMs have shown increased infection rates [8]. In contrast, a sterilized ADM product was able to demonstrate lower infections than the aseptic version, though the sterile version showed significantly higher rates of seroma and

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cellulitis in certain patient populations [9]. Other studies have reported similar outcomes with the use of particular sterile ADMs that resulted in a significant decrease in infection rates but also with a significant increase in seroma complications over the aseptic ADM version [10, 11].

One ADM, DermACELL® (hereafter referred to as D-ADM), may be able to provide the advantages of using an ADM for breast reconstruction while also avoiding the increased complication rates noted for certain other ADM products. This material is produced with a very thorough decellularization process, provided terminally sterilized to a Sterility Assurance Level (SAL) of 1×10^{-6}, stored at ambient temperatures using glycerol-based Preservon® technology, and ready for use without need for rehydration [12]. Together, these properties differentiate D-ADM from other ADMs that may require prolonged preparation prior to implantation [9] and which also may contain higher levels of residual DNA and cellular fragments potentially leading to an inflammatory reaction, such as red breast syndrome [3, 13–15].

The purpose of this study was to critically evaluate and compare the quality of outcomes with the use of D-ADM during tissue expander breast reconstruction. A review of patient charts was performed, and those results were compared with the criteria and outcomes reported in recent studies on the use of human acellular dermis and coverage of tissue expander during breast reconstruction.

Materials and Methods

Design and Objectives

A retrospective chart review was conducted of all patients of the author who underwent breast reconstruction with the use of a support matrix placed below the expander/implant. The author had been using D-ADM at a single-military hospital-based practice for several years and had noted anecdotally improved patient outcomes with fewer complications after use of the product. However, there was a paucity of published papers on this ADM, with the largest only representing 18 implants. D-ADM (DermACELL, LifeNet Health, Virginia Beach, VA) is decellularized and terminally sterilized using low-dose gamma irradiation [12, 16], and the published data have suggested the patented processing techniques could be directly related to the positive outcomes with the product. Given the frequent use of these types of grafts in breast reconstruction surgery, it is imperative to make the most informed decision on product choice to achieve best outcomes, improve patient satisfaction, and reduce reoperations or extra treatments for complications. Therefore, this retrospective chart review was undertaken to evaluate the quality outcomes with the use of D-ADM during tissue expander breast reconstruction. The study hypothesis was that D-ADM would provide equivalent or superior success in breast reconstruction compared with the literature reports for similar materials. An institutional review board (IRB) reviewed and approved the study design and methods. The IRB waived the requirement to obtain patient informed consent as the study was a retrospective chart review of treatment already rendered. There was one implanting surgeon. Surgical case logs were used to identify those patients in which D-ADM was used. Patients who received preoperative radiation therapy or had delayed reconstructions were removed to improve the homogeneity of the population.

Assessment Methods

Data from complications and reconstruction outcomes were gathered and placed in a de-identified database. Results were compared with historical outcomes found in the literature that used human ADMs in breast reconstruction. While this study was not structured as a formal meta-analysis, an extensive search was performed which provided enough articles to give a comprehensive overview for comparison. Statistical significance for all sub-analyses, such as outcomes stratified by cancer, chemotherapy, radiation, or smoking status, was performed using Fisher's exact test on statistical software (PRISM, GraphPad Software, Inc., La Jolla, CA).

Surgical Procedure

Surgical procedures were performed by one surgeon only using similar technique in the majority of cases. All cases were reconstructed by placement of tissue expander which was later exchanged to permanent prosthesis once the volume was deemed adequate and satisfactory by both surgeon and patient. Subpectoral reconstruction with addition of dermal allograft in the lower pole of the breast was performed in all patients except four of the late cases in which total tissue expander coverage and pre-pectoral placement was performed. Initial size usage was 6 cm × 16 cm with most cases moving toward 8 cm x 16 cm to enhance the appearance of the lower pole of the reconstructed breast. Dermal allografts with a size of 16 × 20 cm were used in pre-pectoral reconstruction as described by Woo et al. [17]. Also, all cases were handled in a concomitant fashion with mastectomy followed by immediate tissue expander placement and dermal allograft. No reconstruction was a direct to implant reconstruction.

Results

A total of 38 patients underwent 58 breast reconstructions. Of these reconstructions, all 58 were immediate; 18 (31.0%) were unilateral; and 40 (69.0%) were bilateral. D-ADM was used in all of the patients undergoing breast reconstruction.

Table 1 Demographic information

Number of patients		38	
Number of breasts		58	
Age	Mean	43.0	
	Median	42.5	
	Standard deviation	8.7	
	Range	23–61	
BMI	Mean	26.8	
	Median	26.5	
	Standard deviation	4.4	
	Range	19.7–37.4	
BMI	<30	30	78.9%
	≥30	8	21.1%
Race	African-American	5	13.2%
	White	26	68.4%
	Asian	1	2.6%
	Other	6	15.8%

Comorbidities		*n*	
Diabetic		2	5.3%
Smoker	Current	4	10.5%
Chemotherapy	Pre-reconstruction	5[a]	8.5%
	Post-reconstruction	15[a]	25.9%
Radiotherapy	Pre-reconstruction	0[a]	0.0%
	Post-reconstruction	14[a]	24.1%
Mastectomy	Unilateral	18	47.4%
	Bilateral	20	52.6%
Breast cancer stage	0	3	7.9%
	1	4	10.5%
	2	10	26.3%
	3	5	13.2%
	4	0	0.0%
Interoperative fill, mL	Mean	256.1[a]	
	Standard deviation	127.5[a]	

[a] Refers to number of breast reconstructions

Table 1 shows the demographic information of the patient population. The population contained a low percentage of diabetic (5.3%) and current smoking (10.5%) patients but a relatively higher proportion of patients with a BMI $\geq$ 30 (21.1%). Approximately one-quarter of breast reconstructions received post-reconstruction chemotherapy (25.9%) and slightly less received post-reconstruction radiation therapy (24.1%). Fifty-six breasts (96.6%) in 36 patients demonstrated successful outcomes with a median 27 weeks' time to complete healing. Overall, complications were minimal and are shown in Fig. 1. Two subjects (two breast reconstructions) were considered to have failed outcomes, and postoperative radiation was deemed the cause of failure for both of these patients. In one patient, the ADM was well incorporated and vascularized despite the radiation therapy; however, the wound failed to heal in the radiated field. The second failed patient demonstrated good initial portion but then underwent postoperative radiation therapy with exposure of the tissue expander. While patients that received preoperative radiation were excluded from the study due to its deleterious effects, the three patients (five breasts) that received preoperative chemotherapy were included and no complications were seen in these patients.

The smoking population was comprised of 4 patients and 7 breasts. The only complication seen was one instance of flap necrosis in the right breast at 2 weeks postoperative. This same patient experienced a reconstruction failure in the left breast due to postoperative radiation. All other smoking subjects had successful outcomes with no complications. Thirteen breasts were from patients with a BMI $\geq$ 30 and 45 breasts were from patients with a BMI $<$ 30. Complications were universally higher in the BMI $\geq$ 30 group, including a significant increase in flap necrosis ($p = 0.0472$) (Fig. 2). Twenty-four of the 58 breasts (41.4%) were from patients with a cancer diagnosis. With the exception of two cases of flap necrosis seen in patients without cancer, complication rates were higher from patients presenting with a cancer

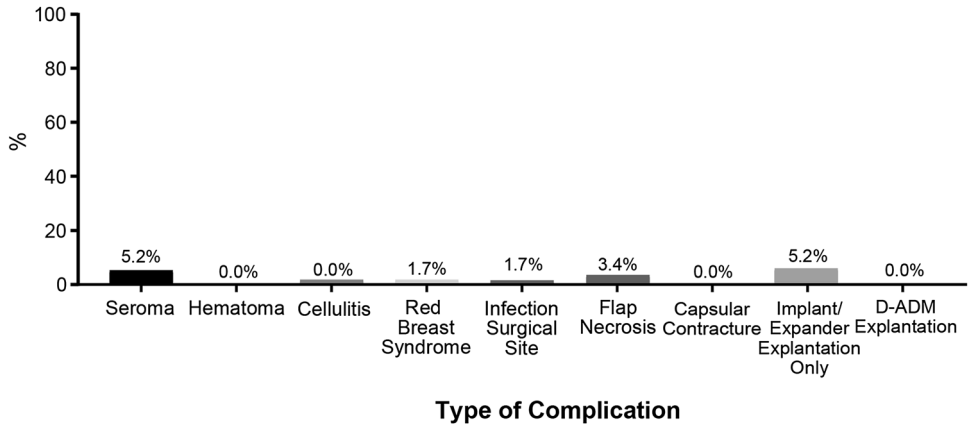

Fig. 1 Complication rates tracked for this cohort of 58 breast reconstructions

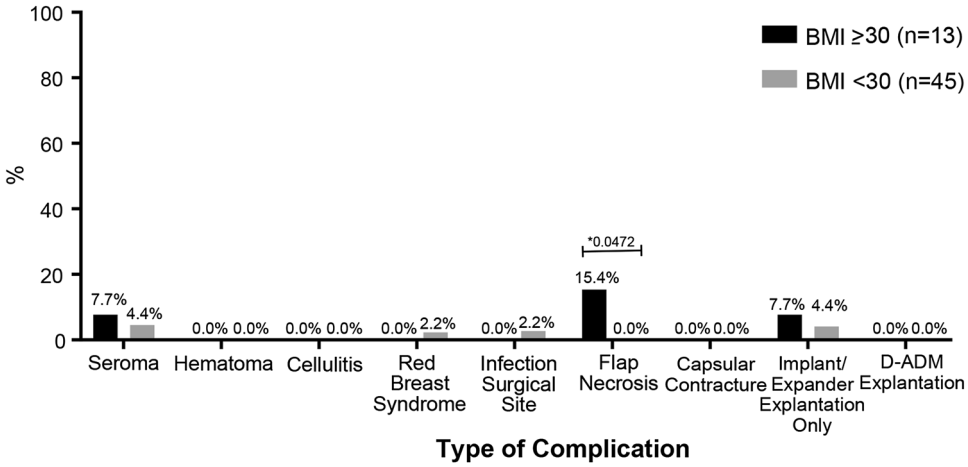

Fig. 2 Complication rates stratified by body mass index (BMI)

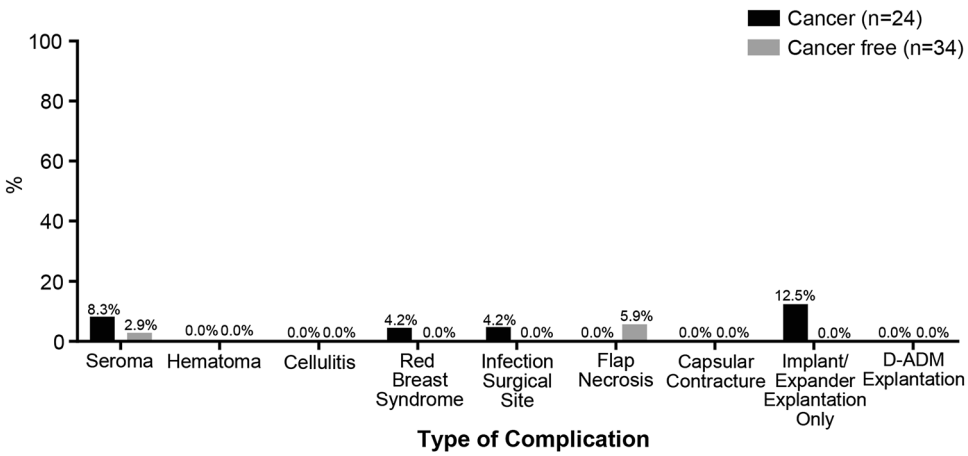

Fig. 3 Complication rates stratified by cancer status

diagnosis (Fig. 3). Similarly, all noted complications were higher in subjects who had undergone postoperative chemotherapy and postoperative radiation therapy except, again, for two instances of flap necrosis (Figs. 4 and 5). Despite the slight edge necrosis, these two patients had successful results with well vascularized and incorporated ADMs as well as good to excellent cosmetic outcomes. Implant and/or expander explantations were significant in groups that received postoperative chemotherapy ($p = 0.0147$) and postoperative radiation ($p = 0.0118$). However, the group of patients with explantations all received both postoperative chemotherapy and radiation

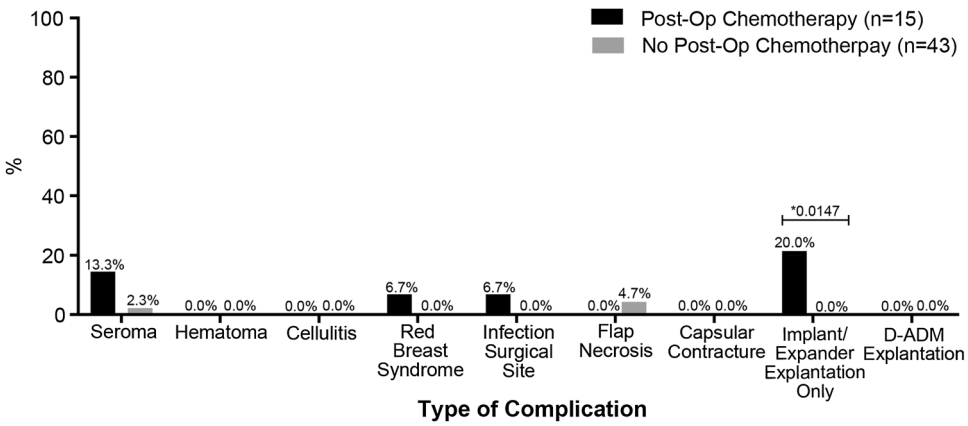

Fig. 4 Complication rates stratified by chemotherapy recipients

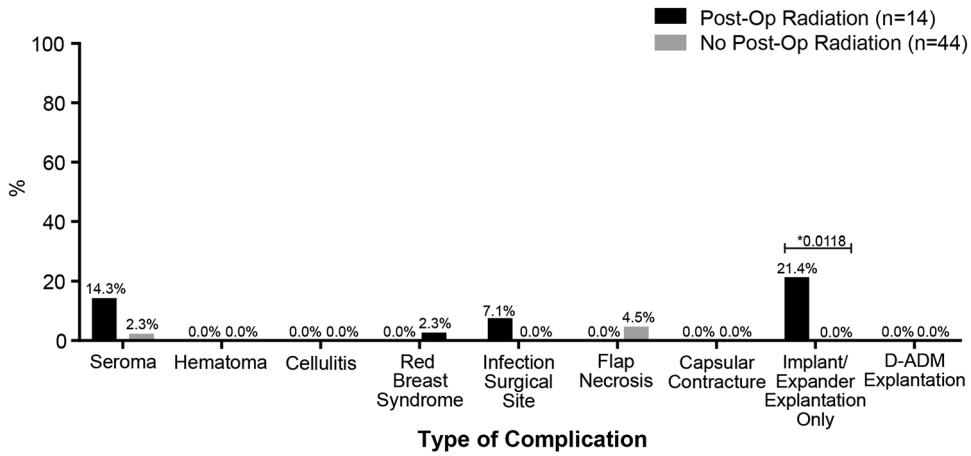

Fig. 5 Complication rates stratified by postoperative radiation recipients

which made it difficult to determine the main correlative factor though the radiation therapy seems probable.

Discussion

The use of acellular dermal matrices as an adjuvant to implant-based reconstruction may have enhanced the ability to address limitations and achieve a better overall esthetic outcome in breast reconstruction, although elevated complication rates are sometimes reported. The results reported here demonstrated a high success rate combined with low complication rates. In addition, the overall failure rate was also low at 3.4% with the two failed reconstructions being attributed to postoperative radiation. Patients who received postoperative radiation also showed significant inclination for explanation of the implant and/or expanders, which could be expected as postoperative radiation has been reported to increase the likelihood for adverse reactions [18–20]. However, it should be noted that no patients in this study, especially including those who underwent postoperative chemotherapy or radiation therapy, had the ADM explanted. This is believed to be secondary to a period of enough time for the D-ADM to become neovascularized during the recovery postoperatively and chemotherapy prior to initiation of radiation therapy. Furthermore, there was a higher trend in reconstructions that received either postoperative radiation or chemotherapy toward seroma development. These patients had received both radiation and chemotherapy, making it difficult to determine whether one or a combination of both cancer treatments are potentially responsible for the increase in seroma development as was also the case with implant and/or expander explantation. Furthermore, although tobacco use has demonstrated a negative effect on wound healing [21, 22], smoking patients reported only a single failed reconstruction and additional complication. That failed reconstruction was believed to be secondary to postoperative radiation, so tobacco use may not have played a role. As the subgroup analyses presented here have low patient populations, these results are included to demonstrate any possible trends on associations between factors such as chemotherapy treatment and patient complications; however, these subgroup results should not be generalized.

Immediate reconstruction using implants has been linked to a higher failure rate in women with severe obesity [23]. Of the 2 failed reconstruction patients, one patient had a BMI above 35. While it is possible that the elevated BMI could have attributed to that failure, the postoperative radiation seems the probable cause. However, the higher overall complication rates in patients with a BMI $\geq$ 30 (Fig. 2) suggested patients with obesity may require greater care and further illustrate the importance of choosing the procedure and materials that will give these patients the greatest chance of success.

The low level of complications reported here with D-ADM compared favorably with the published complication rates of other breast reconstruction studies utilizing ADMs (Table 2). Spear et al. [24] reported 58 acellular dermis-assisted immediate breast reconstructions in 2008 with a postoperative infection rate of 6.9%. Salzberg [4] published a series of 76 immediate single-stage implant breast reconstructions using AlloDerm and reported a 2.6% epidermolysis rate and 1.3% rate of full thickness mastectomy skin flap necrosis with no incidence of infection of seroma. Becker et al. [25] compared two acellular dermal matrices, AlloDerm and DermaMatrix, in 30 patients (50 breasts) who underwent immediate expander-based breast reconstruction and showed no significant differences in complication or material compliance rates with a reported 4% complication rate as a result of one seroma and one infection. However, some studies have shown elevated infection rates in patients receiving certain acellular dermal matrices (Table 2), illustrating that not all ADMs perform similarly and perhaps highlighting the importance of ADM

Table 2 Complication outcomes of breast reconstruction studies ≥ 10 subjects that used human ADM

Ref.	ADM[a]	No. of reconstructions	Seroma	Hematoma	Cellulitis	Red breast syndrome	Infection	Flap necrosis	Capsular contracture	Implant/expander explantation only	ADM explantation	Post-op chemotherapy	Post-op radiotherapy
This study	DermACELL	58	5.2%	0.0%	0.0%	1.7%	1.7%	3.4%	0.0%	5.2%	0.0%	25.9%	24.1%
Antony [1]	AlloDerm	153	7.2%	2.0%	3.9%	–	3.3%	4.6%	–	–	–	28.8%	9.2%
Butterfield [33]	AlloDerm	89	15.7%	0.0%	–	–	6.7%	3.4%	–	11.2%	–	20.0%[b]	6.0%
Chun [2]	AlloDerm	269	14.1%	2.2%	–	–	8.9%	23.4%	–	NQ	–	19.0%	6.5%
Glasberg [32]	AlloDerm	126	12.7%	1.6%	2.4%	14.3%	2.4%	–	2.4%	–	2.4%	–	10.7%
Hanna [34]	DermACELL	252	2.2%	–	–	–	11.8%	1.9%	–	–	–	–	19%
Kim [3]	Meta-analysis		4.8%	1.0%	–	–	5.3%	6.9%	–	–	–	–	
Liu [7]	AlloDerm	266	7.1%	0.4%	–	–	13.5%	13.9%	–	–	–	–	–
Liu [35]	AlloDerm	165	3.0%	1.8%	–	–	8.5%	21.2%	–	4.8%	–	–	-
	FlexHD	97	3.1%	1.0%			14.4%	18.6%		8.2%			-
Mendenhall [36]	AlloDerm	101	6.1%	0.0%	–	–	13.9%	17.8%	–	5.0%	–	–	31.3%
	DermaMatrix	98	3.1%	2.0%			16.3%	21.4%		11.2%			50.0%
Moyer [37]	AlloDerm	22	7.4%	11.1%	–	–	14.8%	–	–	–	–	25.9%	–
Nahabedian [13]	AlloDerm	100	5.0%	–	NQ	NQ	5.0%	3.9%	–	2.0%	1.0%	–	–
Nguyen [38]	AlloDerm	75	–	–	5.3%	–	8.0%	–	–	–	–	–	–
Parks [39]	AlloDerm	346	29.9%	–	–	–	n/a	11.9	–	11.6%	–	–	–
Rawlani [40]	FlexHD	121	1.7%	–	–	–	7.4%	6.6%	–	–	9.1%	–	–
Salzberg [41]	AlloDerm	466		1.1%	–	–	0.2%	1.1%	0.4%	1.3%	–	–	2.1%
Sbitany [6]	AlloDerm	92	6.0%	–	8.0%	–	8%	–	–	–	–	–	
Seth [42]	AlloDerm	136	2.1%	1.3%	–	–	5.2%	9.0%	–	6.4%	–	–	26.5%
	FlexHD	233	1.5%	0.0%			1.5%	3.0%		n/a			21.0%
Vardanian [43]	AlloDerm	208	2.4%[b]	–	–	–	1%	8.25%	3.8%	–	–	–	–
Venturi [44]	AlloMax	65	1.5%	–	–	–	1.5%	3.0%	–	–	–	–	–
Weichman [11]	AlloDerm	90	4.4%	1.1%	20%	–	20%	13.3%	–	6.6%	–	26.7%	14.4%
	AlloDerm RTU	105	1.0%	0.0%	8.5%	–	8.5%	10.4%	–	1.9%		34.3%	5.8%

Table 2 continued

Ref.	ADM[a]	No. of reconstructions	Seroma	Hematoma	Cellulitis	Red breast syndrome	Infection	Flap necrosis	Capsular contracture	Implant/expander explantation only	ADM explantation	Post-op chemotherapy	Post-op radiotherapy
Yuen [9]	AlloDerm	96	18.8%	–	12.5%	–	–	–	–	–	–	–	–
	AlloDerm RTU	100	22%		21.0%	–	–	–	–	–	–	–	–

NQ—not quantified. NQ indicates that the presence of this complication was noted in the study but was not quantified

– Indicates the complication was not reported

[a] Human acellular dermal matrix

[b] Percent of patients and not reconstructions

processing by the different manufacturers. For example, Chun et al. [2] reported an increased incidence for postoperative seroma rates of 14.1 versus 2.7% ($p = 0.0003$), major infections 8.2 versus 0.68% ($p = 0.0016$), and native breast skin flap necrosis rates 23.4 versus 8.9% ($p = 0.0005$) for patients in the AlloDerm cohort. Yuen et al. [9] found complication rates as high as 22% for seroma formation and 21% for cellulitis for AlloDerm-Ready to Use in a retrospective review of 103 patients. The authors concluded their center would discontinue use of this specific ADM in favor of another due to the high complication rates. These high complication rates have not been observed in D-ADM studies. Finally, the complication rates reported here were comparable to the rates reported in a meta-analysis of 19 studies that utilized human ADMs in 2,037 breast reconstructions [3]. The authors noted rates of 4.8% for seroma formation, 5.3% for infection, and the 6.9% for flap necrosis were more than double our flap necrosis rate of 3.2%.

Two previous case series have supported the use of the currently studied D-ADM with promising results in two-stage breast reconstruction. Vashi [26] utilized D-ADM a in two-stage breast reconstruction in ten patients (17 breasts) of which only three were unsuccessful in reconstruction. In a separate case series combined with a histological analysis, Bullocks [27] showed minimal complications from those with healthy lifestyles. As importantly, a detailed histological analysis revealed D-ADM had successfully integrated into the host tissue as demonstrated by the recellularization and revascularization of D-ADM. Yu et al. [28] further explored the histological composition of 24 D-ADM breast capsule biopsies and 24 breast capsule biopsies from the surrounding tissue in 15 patients who underwent breast reconstruction. A blinded pathologist observed significantly less inflammation ($p = 0.001$) and fewer myofibroblasts ($p = 0.024$) in the D-ADM capsules. The lower rates of capsular contracture often seen in ADM patients may result from the ADM preventing inflammatory cells from early capsule formation but the mechanism is not fully understood.

The high rate of successful reconstructions, low rate of complications, and excellent integration into the host tissue may be a result of the processing of D-ADM tissue. D-ADM undergoes a decellularization process, validated to remove $\geq 97\%$ DNA that removes potentially immunogenic material, which could aid in host cellular and vascular ingrowth by providing a biocompatible scaffold [29]. The thorough decellularization process and subsequent terminal sterilization ensure D-ADM has an SAL of 1×10^{-6}, the level of sterilization recommended by the Centers for Disease Control (CDC) for contact with compromised tissue, such as a surgical site. The process is designed to maintain biocompatible and biomechanical properties while also allowing non-freeze-

dried, fully hydrated storage at ambient temperature [12, 30, 31]. These properties, along with the decellularization and terminal sterilization of D-ADM, may explain the low rate seen for red breast syndrome. Red breast syndrome has been observed in breast reconstructions using ADMs [13, 15, 32] but only one other study has quantified the occurrence with a rate of 14% [32]. Our rate of 1.7% (1/58 reconstructions), seen in a single patient who underwent chemotherapy, compared very favorably but future ADM studies should include red breast syndrome so the rate of occurrence can be accurately determined. While ADMs have become a clinical option for breast reconstruction, the increased rate of complications associated with some ADM products has shown the need for more research that especially focuses on complication rates. The study presented here shows that the complication rates associated with D-ADM compare favorably with other ADM products for breast reconstruction.

One weakness of this study was the lack of a randomized control and the corresponding inability to calculate statistical significance for any of the complications presented here. However, a large body of literature currently exists for which the complication and success rates can be compared. As a retrospective study, causation cannot be determined but the purpose here was to undertake a deeper exploration than the previously published case series of the success and complication rates for the use of D-ADM in breast reconstruction. Postoperative radiation can be an obstacle to successful or complication-free outcomes, but the large percentage of patients that underwent radiation therapy here and in many studies listed in Table 2 indicate the need to include this population in breast reconstruction studies to allow for results that can be accurately compared. The encouraging results presented here may provide sufficient justification for a initiating a randomized controlled trial in the future, perhaps even with a third active comparator arm using another human ADM product.

The low complication rates combined with the high success and patient satisfaction rates observed for D-ADM support the use of this ADM in breast reconstruction.

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Compliance with Ethical Standards

Conflicts of interest No other conflicts of interest are disclosed by the author.

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