

# ORIGINAL ARTICLE

# DermACELL Acellular Dermal Matrix in Oncologic Breast Reconstruction: A Cohort Study and Systematic Review

Austin R. Swisher, BS\* Mark J. Landau, MD, PhD+ Nikita Kadakia, MD+ Stephanie W. Holzmer, MD+ Hahns Y. Kim, MD+

**Background:** Acellular dermal matrices (ADMs) are commonly used in tissue expander and direct-to-implant reconstruction following mastectomy. Few studies have reported outcomes of DermACELL use or compared DermACELL with AlloDerm ADM. This study sought to compare outcomes of DermACELL and AlloDerm in oncologic breast reconstruction and to review the literature reporting outcomes of patients undergoing reconstruction using DermACELL.

**Methods:** We conducted a retrospective cohort study to compare outcomes between DermACELL and AlloDerm ADM, and a systematic review of the literature with a meta-analysis to evaluate clinical outcomes with DermACELL.

**Results:** Seventy-four patients (128 breasts) undergoing immediate reconstruction were evaluated retrospectively. Chi-square analysis revealed no significant difference in postoperative outcomes between the two groups. Our systematic review of the literature yielded 12 total studies reporting DermACELL use for breast reconstruction encompassing 518 patients and 608 total breasts. A pooled analysis of the published data did not reveal a significant change in the rate of explantation when either chemotherapy or radiation was used. Meta-analysis did not show a significant difference in the rate of any of the complications evaluated.

**Conclusion:** DermACELL is safe to use with a relatively consistent complication profile as compared with AlloDerm. (*Plast Reconstr Surg Glob Open 2022;10:e4396; doi: 10.1097/GOX.00000000004396; Published online 20 June 2022.*)

# **INTRODUCTION**

Acellular dermal matrices (ADMs) first appeared in the early 1990s and were described in breast surgery as early as 2001.<sup>1</sup> Today, ADMs are commonly used in tissue expander and direct-to-implant reconstruction following mastectomy. ADMs are made from donated skin removed of epidermal layers and major histocompatibility proteins. This decellularization process enhances biocompatibility and incorporation into soft tissues.

ADMs offer positional, structural, and protective support between the implant and skin. Further advantages include better definition of the inframammary fold and

From the \*Department of Surgery, University of California, Riverside School of Medicine, Riverside, Calif.; and †Department of Plastic Surgery, Loma Linda University, Loma Linda, Calif. Received for publication March 4, 2022; accepted May 6, 2022.

Abstract was accepted for presentation at the American Society of Plastic Surgeons Meeting 2021 in Atlanta, GA.

Copyright © 2022 The Authors. Published by Wolters Kluwer Health, Inc. on behalf of The American Society of Plastic Surgeons. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. DOI: 10.1097/GOX.00000000004396 expansion of the lower pole, decreased operative time, improved aesthetic appearance, and a reduction in postoperative pain due to the need for less muscle and less tension placed on the mastectomy skin.<sup>2,3</sup> ADMs are generally accepted as a safe option with low complication rates.<sup>4,5</sup> However, some have reported ADM use increases the risk of complications such as seroma, infection, necrosis, and explantation.<sup>6–12</sup> Moreover, there is a paucity of literature regarding more nuanced questions such as the choice of ADM.

There are several ADM products available on the market, and the effectiveness of different ADM products is clinically significant. DermACELL (LifeNet Health, Virginia Beach, Va.) is a relatively newer ADM offering several potential advantages.<sup>13</sup> It can be stored in ambient temperatures and is ready to use without the need for rehydration or rinsing. DermACELL provides a sterility assurance level of 10<sup>-6</sup> and is proposed to have improved vascular ingrowth and reduced biointolerance.<sup>14,15</sup>

**Disclosure:** The authors have no financial interest to declare in relation to the content of this article.

Related Digital Media are available in the full-text version of the article on www.PRSGlobalOpen.com. Few studies have reported outcomes of DermACELL use or compared DermACELL to other ADMs available on the market, such as the more widely used AlloDerm (LifeCell Corp., Branchburg, N.J.). The purpose of this study was to compare outcomes of DermACELL and AlloDerm in oncologic breast reconstruction and to review the literature reporting outcomes of patients undergoing reconstruction using DermACELL. To our knowledge, this is the first systematic review and meta-analysis of all published outcomes of the use of DermACELL.

# MATERIALS AND METHODS

# **Retrospective Study**

Electronic medical records of patients aged 18–85 years old who underwent unilateral or bilateral, immediate implant-based breast reconstruction from January 2019 through August 2020 at our institution were retrospectively reviewed after institutional review board approval was obtained. Patients without at least 3 months of follow-up were excluded from the study. The mastectomies were performed by one of five surgical oncologists and all reconstructions were performed by the senior author (H.Y.K.).

Baseline demographics, clinical characteristics, postoperative results, and the type of ADM used (AlloDerm or DermACELL) were recorded. Patient demographic data recorded included age, body mass index (BMI), comorbid medical conditions, and anticoagulant, immunosuppressant, tobacco, and drug use. The comorbid medical conditions included hypertension, diabetes, hyperlipidemia, and autoimmune disease. The administration of pre- or postoperative chemotherapy and/or radiotherapy was recorded. Mean duration of drain time was also recorded.

Postoperative complications including seroma, hematoma, minor infection, major infection, skin necrosis, wound dehiscence, capsular contracture, red breast syndrome, and implant failure were defined as those occurring after the reconstruction. Major infections were defined as those requiring hospitalization for intravenous antibiotics. Minor infections were defined as cellulitis or erythema that resolved with oral antibiotics, without the need for hospitalization.

The present study used Microsoft Excel (Microsoft Corp., Redmond, Wash.) to calculate complication rates, SDs, and heterogeneity from chi-square test of independence. A *P* value was defined as less than 0.05 to be considered statistically significant.

# Systematic Review

The study design involved a review of MEDLINE and PubMed databases for human studies published in the English language. The key search terms included "breast reconstruction," "acellular dermal matrix," and "DermACELL." A set of inclusion and exclusion methodology was created based on preferred reporting items for systematic reviews and meta-analyses (PRIMSA) guidelines. In reviewing the titles and abstracts of each article resulting from the database queries, the authors and corresponding

# **Takeaways**

**Question:** How do the reported outcomes of patients undergoing reconstruction using DermACELL compare to the widely used ADM product, AlloDerm?

**Findings:** DermACELL is safe to use with a relatively consistent complication profile as compared to AlloDerm.

**Meaning:** Despite being a relatively new product, surgeons could consider using DermACELL over other available products when appropriate.

institutions of each manuscript were blinded. In our initial screening, we included studies reporting DermACELL outcomes. The references of articles that met inclusion criteria after screening were reviewed further to identify potential studies not originally captured by the preliminary queries.

The characteristics recorded from each study included the number of patients who met inclusion criteria, age, BMI, and sex. We also recorded the use of chemotherapy and/or radiotherapy. The postoperative results included complication data for seroma, hematoma, infection, skin necrosis, wound dehiscence, capsular contracture, red breast syndrome, and implant failure.

Data from each study in the systematic review were weighted based on the number of reported patients meeting inclusion criteria. A pooled analysis to determine the effect of chemotherapy and radiotherapy was evaluated by unpaired *t*-test.

#### Meta-analysis

Following data collection, the results were compiled and a meta-analysis was performed to compare the product outcomes directly. The meta-analysis was conducted using Cochrane Software Review Manager v5.0 (Cochrane Collaboration, Oxford, UK). Risk ratios (RRs) with 95% confidence intervals (CIs) were calculated for dichotomous variables. Homogeneity of risk estimates between studies was assessed using the I<sup>2</sup> statistic.

# **RESULTS**

#### **Retrospective Study**

Between January 2019 to August 2020, a total of 74 patients (128 breasts) undergoing immediate reconstruction by a single surgeon involving DermACELL or AlloDerm ADM were evaluated. The cohort that received DermACELL ADM consisted of 13 patients (25 breasts). The cohort that received AlloDerm ADM consisted of 61 patients (103 breasts). The baseline demographic and clinical characteristics are summarized in Table 1.

The AlloDerm group contained relatively more patient and breast representation in this study. The mean age was similar between the two groups with 48.1 years ( $\pm$ 12.1) for DermACELL and 49.3 years ( $\pm$ 13.1) for AlloDerm (P = 0.74). Mean BMI was also similar between the two groups with 28.0 kg/m<sup>2</sup> ( $\pm$ 5.9) for DermACELL and

Baseline Characteristic	Overall	DermACELL	AlloDerm	Р
Total patients, n (%)	74	13 (17.6)	61 (82.4)	0.65
Total breasts, n (%)	128	25 (19.5)	103 (80.5)	0.23
Mean age, y, SD	$49.1 \pm 12.8$	$48.1 \pm 12.1$	$49.3 \pm 13.1$	0.74
Mean BMI, kg/m <sup>2</sup> , SD	$27.7 \pm 5.4$	$28.0 \pm 5.9$	$27.8 \pm 5.3$	0.91
Median length of follow-up, d	160	140	176	0.09
Smoker, n (%)	12 (16.2)	2 (15.4)	10 (16.4)	0.92
Drug use, n (%)	4(5.4)	0	4 (6.6)	0.39
Diabetes, n (%)	3 (4.1)	0	3 (4.9)	0.46
High blood pressure, n (%)	15 (20.3)	4 (30.8)	11 (18.0)	0.24
Hyperlipidemia, n (%)	15 (20.3)	3 (23.1)	12 (19.7)	0.64
Autoimmune condition, n (%)	4 (5.4)	0	4 (6.6)	0.39

**Table 1. Baseline Demographic and Clinical Characteristics** 

27.8 kg/m<sup>2</sup> (±5.3) for AlloDerm (P = 0.91). The proportion of patients with high blood pressure was different between the two groups with four DermACELL patients (30.8%) and 11 AlloDerm patients (18.0%), although this difference was not statistically significant. The other baseline characteristics (smoking and hyperlipidemia) were similar between the two groups.

Clinical outcomes, separated by the type of ADM used and calculated as a proportion of total breasts, are summarized in Table 2. Chemotherapy and radiotherapy received at any point during the study occurred at a rate of 40.0% versus 53.4% (P=0.92) and 24.0% versus 19.4% (P=0.31) for the DermACELL and AlloDerm groups, respectively. The DermACELL group had lower rates of hematoma formation (DermACELL: 4.0% versus AlloDerm: 4.9%, P = 0.95), delayed wound healing (4.0% versus 13.6%, P = 0.34), skin necrosis (0% versus 16.5%, P = 0.08), implant loss/failure (16% versus 21.4%, P = 0.97), and minor infection (8.0% versus 12.6%, P = 0.80). The DermACELL group had a higher rate of major infection (20.0% versus 12.6%, P = 0.16) and explanation for infection (16.0% versus 11.7%, P = 0.30). However, none of these differences were statistically significant. The complication rates for seroma (4.0% versus 10.7%, P = 0.49), red breast syndrome (0% versus 1.0%, P = 0.67), and capsular contracture (4.0% versus 4.9%, P = 0.95) were similar between the two groups. There was also no significant difference in time to drain removal (14.6 versus 16.6 days, P = 0.13). One patient from each group required a return to the operating room for hematoma, and one patient in the AlloDerm group who underwent explantation for

infection elected to undergo contralateral explantation for symmetry.

Three DermACELL patients underwent either adjuvant or neoadjuvant radiation. One patient experienced capsular contracture and cellulitis in the irradiated breast, but none of the patients had a major complication requiring explantation.

#### Systematic Review

We systematically reviewed the literature describing results of DermACELL use in breast reconstruction (Fig. 1). Twelve papers were included in final analysis. Overall, the systematic review encompassed 518 patients and 608 total breasts. The complication data are summarized in Table 3.

Seven studies reported the average patient age and the use of pre- and/or postoperative radiotherapy, and six studies reported patient BMI and the use of preand/or postoperative chemotherapy. A pooled analysis of the published data did not reveal a statistically significant difference in the rate of explantation for infection when either chemotherapy (chemotherapy: 13.0% versus no chemotherapy: 6.0%, P = 0.31) or radiation (radiation: 8.6% versus no radiation: 9.1%, P = 0.91) were used.

The included studies reported data by patient, by breast, or both. More studies presented data by breast than by patient alone. Thus, outcomes data were compiled based on those studies reporting complications in terms of the number of breasts (nine of 12 studies). Of the three studies not included in Table 3, one reported data

	Overall	DermACELL	AlloDerm	
Clinical Outcomes	n = 128	n = 25	n = 103	Р
Mean duration of drain time, d, SD	$16.0 \pm 6.6$	$14.6 \pm 5.7$	$16.7 \pm 6.7$	0.13
Seroma, n (%)	12 (9.4)	1 (4.0)	11 (10.7)	0.49
Hematoma, n (%)	6 (4.7)	1 (4.0)	5 (4.9)	0.95
Minor infection, n (%)	15 (11.7)	2 (8.0)	13 (12.6)	0.80
Major infection, n (%)	18 (14.1)	5 (20.0)	13 (12.6)	0.16
Explantation, n (%)	16 (12.5)	4 (16.0)	12 (11.7)	0.30
Delayed healing, n (%)	15 (11.7)	1(4.0)	14 (13.6)	0.34
Skin necrosis, n (%)	17 (13.3)	0	17 (16.5)	0.08
Implant failure, n (%)	26 (20.3)	4 (16.0)	22 (21.4)	0.97
Wound dehiscence, n (%)	7 (5.5)	1(4.0)	6 (5.8)	0.92
Capsular contracture, n (%)	6 (4.7)	1 (4.0)	5 (4.9)	0.95
Red breast syndrome, n (%)	1 (0.78)	0	1 (1.0)	0.67
Chemotherapy received at any point, n (%)	65 (50.8)	10 (40.0)	55 (53.4)	0.95
Radiotherapy received at any point, $n(\%)$	26 (20.3)	6 (24.0)	20 (19.4)	0.30

Table 2. Comparison of Clinical Outcomes of DermACELL and AlloDerm



Fig. 1. Flowchart of selection process of articles in the systematic review.

only by patients and the other two studies reported data only for drainage duration. In our pooled data analysis, the most commonly reported complication was delayed wound healing (11.8%), followed by infection (5.7%), skin necrosis (5.5%), and wound dehiscence (5.1%). The overall incidence of explantation for infection was 3.4%(range: 0%–11.1%).

Outcomes from our pooled analysis compared favorably to those from our cohort (Table 4). However, the rates of infection (overall: 5.7% versus Swisher: 20.0%), explantation (3.4% versus 16.0%), and implant loss/failure (2.5% versus 16.0%) were higher in our study.

#### Meta-analysis

We conducted a meta-analysis of included studies that directly compared outcomes of DermACELL and AlloDerm using a random-effect model. [See figure, Supplemental Digital Content 1, which displays the metaanalysis of outcomes of DermACELL versus AlloDerm. (A) Implant failure, (B) skin necrosis, and (C) hematoma, http://links.lww.com/PRSGO/C70; See figure, Supplemental Digital Content 2, which displays (A) seroma, (B) red breast syndrome, (C) infection, (D) drain removal (days). The black diamond the represents the 95% CI, http://links.lww.com/PRSGO/C71.]

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Our meta-analysis did not reveal a significant difference in the rate of any complication. This included implant failure (RR: 1.29, 95% CI: 0.65-2.56, P = 0.46,  $I^2 = 0\%$ ), skin necrosis (RR: 0.83, 95% CI: 0.33-2.10, P = 0.69,  $I^2 = 0\%$ ), hematoma (RR: 0.59, 95% CI: 0.18– 1.89, P = 0.38,  $I^2 = 0\%$ ) [See figure, Supplemental Digital Content 1, http://links.lww.com/PRSGO/C70], seroma (RR: -0.03, 95% CI: -0.12 to 0.05, P = 0.46,  $I^2 = 44\%$ ), red breast syndrome (RR: 0.15, 95% CI: 0.02–1.21, P=0.08, I<sup>2</sup> = 39%), infection (RR: 0.98, 95% CI: 0.25–3.82, P = 0.97,  $I^2 = 37\%$ ), and drain duration (RR: -0.98, 95% CI: -2.15) to 0.18, P = 0.10,  $I^2 = 53\%$ ). [See figure, Supplemental Digital Content 2, http://links.lww.com/PRSGO/C71.] The incidence of red breast syndrome and days to drain removal were both decreased in cases using DermACELL, with results trending toward significance.

#### DISCUSSION

With a growing emphasis on value-based care, it is of the utmost importance for both patient safety and cost optimization to determine the best standard of care possible. The use of ADMs has become standard practice in tissue expander and direct-to-implant reconstruction following mastectomy.<sup>16,17</sup> Complete implant coverage

	_					Delaved	Skin	Implant	Manud	Cancular	Red Breact
Author (Reference),Country	Sample	Seroma Rate, %	Infection Rate, %	Hematoma Rate, %	Explantation Rate, %	Healing Rate%	Necrosis Rate %	Failure Rate, %	Dehiscence Rate, %	Contracture Rate, %	Syndrome Rate, %
Arnaout et al, <sup>28</sup> Canada	33 patients,	12.5	10.0	0	5.0	N/D	12.5	5.0	7.5	0	2.5
Bilezikian et al, <sup>51</sup> USA	131 patients,	0	4.3	N/D	4.3	N/D	N/D	0	N/A	0	N/D
Bullocks, <sup>14</sup> USA	10 patients,	22.2	11.1	0	11.1	22.2	16.7	22.2	N/D	N/D	0
Chang and Liu, <sup>24</sup> USA	14 patients,	0	0	0	0	N/D	0	0	5.0	N/D	0
Greig et al, <sup>13</sup> Canada	20 Dreasts 36 patients,	8.9	14.3	5.4	7.1	N/D	7.1	3.6	N/D	12.5	1.8
Ortiz, <sup>52</sup> USA	38 patients,	5.2	1.7	0	N/D	N/D	3.4	5.2	3.4	0	1.7
Pittman et al, <sup>38</sup> USA	30 patients,	10.0	4.0	0	0	8.0	8.0	0	N/D	N/D	0
Vashi, <sup>26</sup> USA	9 patients, 17	N/D	N/D	N/D	N/D	N/D	N/D	5.9	N/D	0	0
Zenn and Salzberg, <sup>27</sup> USA	Dreasts 70 patients, 110 hooses	0.0	N/D	N/D	0.0	N/D	1.7	N/D	N/D	N/D	N/D
Overall weighted average by breast Comparison to Swisher et al retrospective cohort data for DermACELL	119 Dreasus 13 patients, 25 breasts	$\frac{3.7}{4.0\ (1/25)}$	$\frac{5.7}{20.0(5/25)}$	$\substack{1.2 \\ 4.0 \ (1/25)}$	$\begin{array}{c} 3.4 \\ 16.0 \ (4/25) \end{array}$	$\frac{11.8}{4.0\ (1/25)}$	0.5	2.5 16.0 (4/25)	$5.1 \\ 4.0 \ (1/25)$	$\begin{array}{c} 1.8 \\ 4.0 \; (1/25) \end{array}$	$\begin{array}{c} 1.2\\ 0\end{array}$
N/D, no data.											

using ADM reduces the risk of exposure, capsular contracture, and an unnatural breast step-off.<sup>4,18,19</sup> The use of ADMs may also improve patient satisfaction.<sup>20-22</sup> However, the relative effectiveness between the different available products has not been adequately tested, especially for DermACELL.23 The question of which ADM to use is convoluted, with mixed or negligible differences in complication rates. This problem is compounded by several other factors to consider, such as drainage duration, cosmetic outcomes, ease of use, and cost.<sup>10</sup>

Studies assessing ADMs are inherently biased with conflicts of interest.<sup>24</sup> Proponents of DermACELL, which entered the market in 2010, comment on its superior level of decellularization and that it does not require dehydration or rinsing before use.<sup>25–27</sup> Conversely, proponents of AlloDerm point to more established data regarding its safety and efficacy.<sup>26,28,29</sup> The cost associated with ADMs is also a factor worthy of consideration. Previous studies have reported DermACELL as being more expensive than AlloDerm; however, the cost for each may vary by institution.<sup>30</sup>

The aseptic process of both products comes with an inherent risk as preexposure to gentamicin and vancomycin may contraindicate the use of ADMs in patients with antibiotic sensitivities.<sup>15,30</sup> Nevertheless, these products appear to be safe and there does not appear to be any difference in long-term outcomes between the two ADMs.<sup>31,32</sup>

The present study attempted to elucidate the potential superiority of DermACELL or AlloDerm by comparing their outcomes. The baseline demographic and clinical characteristics were similar between the two groups (Table 1). The median length of follow-up for AlloDerm was greater by 36 days (P = 0.09).

We showed the complication rates and drain duration were statistically similar between the two groups. The time to drain removal was on average 2.1 days less in the DermACELL group than in the AlloDerm group (P =0.13) in our cohort. Likewise, the overall effect found for drain duration in our meta-analysis neared significance (P = 0.10). We did not include our unpublished data in the meta-analysis. If permitted, however, the meta-analysis would have yielded a significant decrease in drain duration for cases using DermACELL as compared to AlloDerm (RR: -1.10, 95% CI: -2.17 to -0.03, P = 0.04). These findings support the direction of other studies which have reported significant differences in the total number of days to drain removal in favor of DermACELL.24,33-36 This trend may be explained by subtle differences in the fenestrations of the natural material, which could allow fluid from the ADM to escape and facilitate more efficient drainage.<sup>37</sup> This could also be due to DermACELL's advantage in promoting host tissue integration and revascularization. One study using in vivo rat models found that vessel ingrowth with DermACELL nearly doubled that of AlloDerm, providing a theoretical mechanism for the resolution of inflammation and edema.<sup>15</sup>

The complication rates for seroma, red breast syndrome, and capsular contracture in our study were similar between the two groups. This finding seems to be validated by Greig et al<sup>13</sup> who found no differences in seroma,

Complication	Overall Rate, %	Swisher et al. Rate, %	Total Range, %	No. Studies Reporting
Seroma	3.7	4.0	0-22.2	8
Infection	5.7	20.0	0-11.1	7
Hematoma	1.2	4.0	0-5.4	6
Explantation	3.4	16.0	0-11.1	6
Delayed healing	11.8	4.0	8-22.2	2
Skin necrosis	5.5	0	0 - 16.7	6
Implant failure	2.5	16.0	0-22.2	8
Wound dehiscence	5.1	4.0	3.4 - 7.5	3
Capsular contracture	1.8	4.0	0 - 12.5	5
Red breast syndrome	1.2	0	0-2.5	7

Table 4. Summary of Weighted Systematic Review Outcomes Compared to Swisher et al

hematoma, flap necrosis, and infection in a retrospective study of 64 patients. Likewise, Zenn and Salzberg<sup>27</sup> studied 140 patients and found no difference in infection, implant loss, or hematoma, concluding that each ADM product was safe.

It should be noted that the DermACELL group had atypical rates of major infection (20.0%). This high infection rate could be due to our study's limitations of a small sample size. The DermACELL cohort consisted of only 13 patients and was therefore subject to greater variance. This entailed five breasts out of 25 total breasts, and four of these breasts were explanted for infection. Without operational definitions, a substantial problem in the literature exists for reporting infections. These reporting errors may explain discrepancies in standard infection rates, which can range from 0% to 24% in breast reconstruction.<sup>38,29</sup>

Several studies have shown smoking, BMI, chemotherapy, and radiation therapy serve as independent risk factors for complications in breast reconstruction.<sup>40</sup> Remington et al<sup>41</sup> in a cohort study of 166 patients undergoing breast reconstruction using AlloDerm found the overall infection rate to be 16.9%, and a BMI greater than 27.0 was significantly associated with this finding. Hill et al.<sup>42</sup> studied 79 patients over a 5-year period and found ADM use combined with smoking was associated with a 37% risk for infection. These studies shed light on our study, which included patient characteristics with an overall BMI of 27.7 kg/m<sup>2</sup> and smoking accounted for in 16.2% of the patients between the two groups.

Additionally, the DermACELL group in our study included a high rate of high blood pressure (30.8%). Studies have found comorbid conditions such as high blood pressure are associated with increased failure rate, and BMI greater than  $30 \text{ kg/m}^2$  may lead to increased explanation.<sup>43–45</sup> Overall, the implications of our study's complication rates confirm the need for a stratified approach in reporting for future research to improve preoperative counseling and informed decision-making.

The rate of skin necrosis in our study was higher in the AlloDerm group, although this difference was not statistically significant. The rate of 16.5% is above the normal range reported in the literature for necrosis when using AlloDerm (<14%).<sup>12,13,45–48</sup> This finding may offer a potential benefit of using DermACELL over AlloDerm. However, in a meta-analysis, Wu et al<sup>49</sup> found no difference in the rate of necrosis (RR: 0.49, 95% CI: 0.12–1.89, P = 0.30) between AlloDerm and DermACELL.

Our systematic review found delayed wound healing for DermACELL occurred at the highest rate of all the complications (11.8%). However, this outcome was not heavily reported in the literature and thus was only represented by two studies or a total of 72 breasts. A delayed wound healing rate of 11.8% would be high. Another systematic review of AlloDerm use in postmastectomy patients found delayed wound healing to occur at a rate of 0.5%.<sup>50</sup> The increased rate produced from our study's systematic review may implicate a potential disadvantage of DermACELL, but this conclusion is subject to a small sample size with limited evidence and would seem to disagree with the rate found in our cohort data (4.0%). This underscores how our systematic review data was limited by nonstandardized reporting of outcomes. Table 3 excluded three of the final 12 studies because the data was presented by patient only, whereas all the other studies presented data by breasts. Thus, more research with greater standardization is needed.

The remaining complication rates for seroma, infection, hematoma, explantation, necrosis, implant failure, capsular contracture, wound dehiscence, and red breast syndrome gathered from the systematic review all occurred at a rate of 5.7% or lower. These data agree with Arnaout et al.'s head-to-head comparison of DermACELL and AlloDerm.<sup>28</sup> It is difficult to determine the standardized range for each of these respective outcomes because there has not been substantial data collected using DermACELL.

Our retrospective cohort study was limited by a relatively small sample size and lack of standardized follow-up. The retrospective nature of this study did not permit randomization and therefore was not protected against the possibility of selection bias. Although the breast reconstruction was performed by the same surgeon (H.Y.K.), the mastectomies were performed by several surgical oncologists and the data do not account for possible differences in the mastectomy technique. A comparison of outcomes of staged reconstruction versus direct-to-implant reconstruction was beyond the scope of this study, but remains an important consideration worthy of investigation in future comparisons of ADMs.

Despite these limitations, our study provides new data regarding outcomes of breast reconstruction with ADMs. Our study as a whole suggests DermACELL's efficacy is comparable to Alloderm in postmastectomy reconstruction. However, more research is required to contextualize the use of DermACELL and the other various ADM options available.

# CONCLUSIONS

DermACELL is safe to use with a relatively consistent complication profile as compared with AlloDerm. DermACELL may have the advantages of reduced incidence of red breast syndrome, capsular contracture, necrosis, drain removal time, and improved vascular ingrowth. However, more research with increased sample sizes and stratification of variables should be conducted. A greater degree of standardization is needed when reporting outcomes that compare ADM products available on the market.

#### Hahns Y Kim, MD

11175 Campus Street, Suite 21126 Loma Linda, CA 92350 E-mail: hahkim@llu.edu

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