OPEN

PRS GLOBAL OPEN

ORIGINAL ARTICLE

Breast

Comparison of 30-day Clinical Outcomes with SimpliDerm and AlloDerm RTU in Immediate Breast Reconstruction

Brian P. Tierney, MD

Background: Acellular dermal matrix (ADM) is widely used in breast reconstruction, and outcomes of these procedures may be improved through optimized product design. SimpliDerm is a new human ADM designed to closely preserve the architecture of native dermis, with the goal of improving surgical outcomes. This study reports the initial (30-day) clinical experience with SimpliDerm compared with AlloDerm Ready-To-Use (RTU) in ADM-assisted breast reconstruction.

Methods: Clinical characteristics and outcomes of 59 consecutive patients who underwent immediate 2-stage reconstruction with SimpliDerm (n = 28) or AlloDerm RTU (n = 31) following mastectomy are reported.

Results: Fifty-nine women (108 breasts) underwent posmastectomy breast reconstruction with SimpliDerm or AlloDerm RTU. Mean patient age was 51.1 years, and mean body mass index was 28.2 kg/m^2. Reconstructions were predominantly prepectoral (95.4%), used tissue expanders (100%), and followed a skin-sparing (64%) approach to mastectomy. Mean time to final drain removal did not differ between groups (17.0 days, SimpliDerm versus 17.7 days, AlloDerm RTU). Adverse events occurred in 13 (22%) patients; none considered serious—all were mild or moderate in intensity. Adverse event rates did not differ between groups. The observed adverse event profiles and rates are similar to those published for other ADMs in immediate breast reconstruction.

Conclusions: There remains a clinical need for ADMs with more optimal characteristics. This case series describes comparable outcomes with SimpliDerm and AlloDerm RTU over 30 days after immediate 2-stage breast reconstruction.
(Plast Reconstr Surg Glob Open 2021;9:e3648; doi: 10.1097/GOX.0000000000003648; Published online 16 June 2021.)

INTRODUCTION

Acellular dermal matrices (ADMs) have been utilized to augment soft tissue repairs for over two decades. Initially targeted for wound treatment, ADMs have recently been used to provide structural strength to applications such as breast reconstruction. Indeed, over 100,000 breast reconstructions are performed each year in the United States, with over 60,000 utilizing ADM.[1] Widespread use of ADM for prosthetic breast reconstruction provides multiple benefits, including lower pole and inframammary fold support, implant or tissue expander stabilization, prepectoral placement implant coverage, greater initial expander fill volumes in two-stage reconstructions, improved cosmetic outcomes, and reduced capsular contracture risk.[2–8] Commercially available ADMs derive from different species and tissue sources (eg, human, bovine, porcine; dermis, pericardium, intestinal submucosa) and are processed using differing methods of decellularization, antigen removal, and sterilization. Consequently, different ADM products have distinct physical and biological characteristics resulting from their unique processing methods.

The reported comparable complication rates and handling characteristics of ADMs used for breast reconstruction suggest an opportunity to improve performance through optimized product design.[9,10] SimpliDerm (Aziyo Biologics, Silver Spring, Md.) is a new human ADM (hADM) product manufactured using patented processes designed to better preserve the characteristics of native tissue, such as the extracellular matrix (ECM) and the biologically active mediators embedded therein. Extensive evidence indicates

From Tierney Plastic & Reconstructive Surgery, Nashville, Tenn.
Received for publication February 11, 2021; accepted April 27, 2021.

DOI: 10.1097/GOX.0000000000003648

Disclosure: *Dr Tierney is a consultant for Aziyo Biologics.*

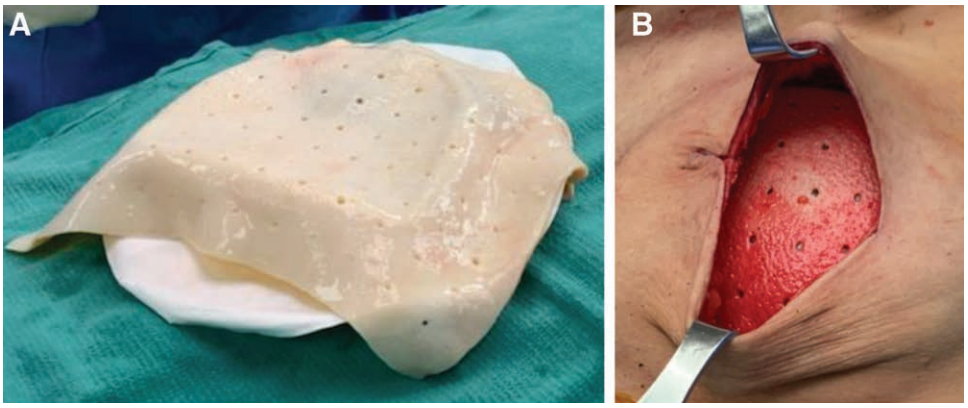

Fig. 1. Prepectoral ADM-assisted breast reconstruction with SimpliDerm. A, Positioning of the ADM over the selected tissue expander in preparation for placement in the breast. B, The ADM-covered tissue expander was inserted into the prepectoral plane and sutured to the pectoralis major muscle and inframammary fold.

that greater preservation of ECM structure in ADMs fosters integration into native tissues, robust revascularization, and a constructive inflammatory response.[11–14]

Recent work in a nonhuman primate model of abdominal wall repair demonstrated some of the potential advantages of the hADM SimpliDerm.[15] In this model, measures of inflammation and fibrosis-related tissue remodeling were compared between SimpliDerm and the hADM AlloDerm ready-to-use (RTU) (Allergan Medical, Irvine, Calif.). Compared with AlloDerm RTU, SimpliDerm demonstrated a lower initial inflammatory response, slower implant degradation, and lower expression of proinflammatory cytokines and pro-fibrotic markers over time. Together, these findings suggest that SimpliDerm is associated with a reduced inflammatory and fibrotic response and improved constructive remodeling compared with AlloDerm RTU after pre-clinical implantation.

To explore the clinical efficacy and safety of this new hADM for breast reconstruction, we report the initial 30-day clinical experience with SimpliDerm compared with the older hADM AlloDerm RTU (now called AlloDerm SELECT Regenerative Tissue Matrix) in immediate, two-stage breast reconstructions.

METHODS

The retrospective experience of two ADMs used by one surgeon was analyzed. A central review board (WIRB) approved the review. The review was limited to patients who underwent immediate breast reconstruction following mastectomy. Patients who underwent cosmetic/aesthetic breast augmentation or revision, delayed breast reconstruction, or revision of previous breast reconstruction procedure were not included. The charts of 59 consecutive patients (108 breasts) who underwent immediate, two-stage, tissue expander–based breast reconstruction with the use of SimpliDerm (28 patients, 53 breasts) or AlloDerm RTU (31 patients, 55 breasts) were reviewed. Reconstructions were completed between January 2020 and October 2020.

Use of either hADM brand was based on facility availability at that time, and both hADMs were prepared according to the respective manufacturer's instructions. To support reconstruction, the hADM was draped over the tissue expander and sutured to the pectoralis major muscle and inframammary fold, as described by previous studies (Fig. 1).[2,6,7] All patients underwent the same intraoperative two-drain protocol for both perforated and nonperforated ADMs: each treated breast received one subcutaneous drain and one drain placed in the sub-ADM periprosthetic space. This drain protocol was followed no matter the brand of ADM used. The treating surgeon has extensive experience with ADM-based breast reconstruction, and surgical technique did not differ between the two products.

Postoperatively, patients were observed for 23 hours and discharged from the hospital the day after their procedure. Typical follow-up consisted of in-office visits at week 1 to remove the first set of drains, week 2 to remove the second (and final) set of drains, and week 3 to begin tissue expansion. However, final drain removal was only performed once output volume dropped below 30 mL per 24 hours. A standard postoperative antibiotic course was followed for every treated patient (prophylactic oral doxycycline for one week).

Demographic data, medical history, examination findings, surgical details, and assessment of peri- and postoperative outcomes and complications were collected and analyzed. Following assessment for normality, the overall cohort was described using counts with percentages and means with SDs. Patient demographics and treatment characteristics were compared between the AlloDerm RTU and SimpliDerm cohorts using independent samples t-tests and chi-square tests. Pearson chi-squares were reported when all expected cell counts were five or greater, alternatively Fisher's exact tests are provided. Statistical significance was set to $P < 0.05$.

RESULTS

A total of 59 women (108 breasts) underwent postmastectomy breast reconstruction with either SimpliDerm or AlloDerm RTU. Postprocedure patient follow-up did not

differ between groups, and averaged 24.9 ± 4.8 days for SimpliDerm and 22.3 ± 6.0 days for AlloDerm RTU. There were no statistically significant differences between groups for patient age, race, ethnicity, body mass index, smoking status, medical history, or pretreatment medications, chemotherapy, or radiotherapy (Table 1). A total of 19 subjects (32%) received chemotherapy before reconstruction (10 AlloDerm RTU, nine SimpliDerm). One patient in the AlloDerm RTU group received preprocedural radiotherapy, and one patient in the SimpliDerm group received both radiotherapy and chemotherapy before the procedure.

Procedural details are summarized in Table 2. The majority of reconstructions used a prepectoral implant placement (103 breasts, 95%). Five patients in the AlloDerm RTU group and zero in the SimpliDerm group had subpectoral reconstructions (P = 0.025). In both groups, most reconstructions were bilateral (87.3% AlloDerm RTU, 94.3% SimpliDerm). Intraoperative expander fill volumes, perforation of the hADM, mastectomy type (skin-sparing versus nipple-sparing), and mastectomy indication did not differ between groups.

The patients' 30-day postoperative course is summarized in Table 3. No patients in either group received radiotherapy or combined chemotherapy and radiotherapy during follow-up. Two subjects (7%) in the SimpliDerm group and zero in the AlloDerm RTU group received postmastectomy chemotherapy (P = NS). There were no significant differences between groups in use of pain medication, anticoagulants, antibiotics, or other medications during follow-up. Mean time to last drain removal was 17.7 ± 4.6 days with AlloDerm RTU and 17.0 ± 4.9 days with SimpliDerm (P = NS).

Postprocedural complications occurred in six (19.4%) AlloDerm RTU subjects and seven (25.0%) SimpliDerm subjects (P = NS), of which five (83.3%) and four (57.1%), respectively, required surgical intervention (Tables 3, 4). One subject in each group had a complication that resulted in explantation. None of the reported adverse events were considered serious, and all were of mild or moderate severity (Table 4). The adverse events identified in the AlloDerm RTU group were flap ischemia (n = 4, 66.7%) and hematoma (n = 2, 33.3%). There were no hematoma identified in the SimpliDerm group. Adverse events identified with SimpliDerm included infection (n = 1, 14.3%), flap ischemia (n = 4, 57.1%), seroma (n = 1, 14.3%), and one small skin pinhole with surrounding redness (14.3%).

DISCUSSION

Despite increasing experience supporting the utility of ADMs in breast reconstruction,[16,17] there remains an unmet need for ADMs with more optimal clinical characteristics. AlloDerm has been used to support postmastectomy breast reconstruction for more than a decade and has demonstrated comparable clinical outcomes to other ADMs, with similar complication types and rates.[4,10,18–24] The results of this preliminary study describe similar initial (30-day) outcomes between a new hADM, SimpliDerm, and AlloDerm RTU in immediate, two-stage breast reconstructions. To

Table 1. Patient Demographics

Characteristic	AlloDerm RTU (n = 31, 52.5%)	SimpliDerm (n = 28, 47.5%)	*P*
Age, y (mean ± SD)	51.1 ± 11.9	51.2 ± 12.5	0.980
Race			0.763
White	22 (71.0%)	22 (78.6%)	—
Black or African American	8 (25.8%)	5 (17.9%)	—
Asian	1 (3.2%)	1 (3.6%)	—
Ethnicity			0.338
Non-Hispanic or Latino	30 (96.8%)	28 (100.0%)	—
Hispanic or Latino	1 (3.2%)	0 (0.0%)	—
Body mass index, kg/m^2 (mean ± SD)	28.5 ± 6.3	27.9 ± 6.0	0.689
Body mass index category (kg/m^2)			0.999
Normal (18.5 to <25.0)	10 (32.3%)	9 (32.1%)	—
Overweight (25.0 to <30.0)	9 (29.0%)	8 (28.6%)	—
Obese (30.0 to <40.0)	12 (38.7%)	11 (39.3%)	—
Smoking			0.089
Never	27 (87.1%)	24 (85.7%)	—
Former	4 (12.9%)	1 (3.6%)	—
Current	0 (0.0%)	3 (10.7%)	—
Medical history			—
Previous or current cancer diagnosis	30 (96.8%)	26 (92.9%)	0.494
Diabetes	4 (12.9%)	2 (7.1%)	0.465
Hypertension	8 (25.8%)	9 (32.1%)	0.592
Hypercholesterolemia	7 (22.6%)	4 (14.3%)	0.414
Other	15 (48.4%)	14 (50.0%)	0.902
Pretreatment medication type			—
Cancer treatment medication	0 (0.0%)	2 (7.1%)	0.130
Anticoagulant	0 (0.0%)	1 (3.6%)	0.289
Pretreatment chemotherapy or radiotherapy			0.630
Unknown	1 (3.2%)	0 (0.0%)	—
No	19 (61.3%)	18 (64.3%)	—
Yes	11 (35.5%)	10 (35.7%)	—
Type			0.366
Chemotherapy	10 (90.9%)	9 (90.0%)	—
Radiotherapy	1 (9.1%)	0 (0.0%)	—
Both chemotherapy and radiotherapy	0 (0.0%)	1 (10.0%)	—

Table 2. Procedural Details, by Breast (N = 108)

Variable	AlloDerm RTU (n = 55, 50.9%)	SimpliDerm (n = 53, 49.1%)	*P*
Plane of expander/implant placement			0.025
Prepectoral	50 (90.9%)	53 (100.0%)	—
Subpectoral	5 (9.1%)	0 (0.0%)	—
Intraoperative expander fill volume, cm^3 (mean ± SD)	391.8 ± 83.2	386.8 ± 101.0	0.777
hADM perforated versus not	21 (38.2%)	29 (54.7%)	0.085
Mastectomy type			0.456
Skin-sparing	37 (67.3%)	32 (60.4%)	—
Nipple-sparing	18 (32.7%)	21 (39.6%)	—
Bilateral or unilateral			0.367
Bilateral	48 (87.3%)	50 (94.3%)	—
Unilateral—left	4 (57.1%)	1 (33.3%)	—
Unilateral—right	3 (42.9%)	2 (66.7%)	—
Mastectomy indication			0.375
Malignancy (therapeutic)	53 (96.4%)	49 (92.5%)	—
Prophylactic	2 (3.6%)	4 (7.5%)	—

Table 3. Follow-up and Complications, by Patient (N = 59)

Variable	AlloDerm RTU (n = 31, 52.5%)	SimpliDerm (n = 28, 47.5%)	*P*
Follow-up time, days (mean ± SD)	22.3 ± 6.0	24.9 ± 4.8	0.073
Time to last drain removal, d (mean ± SD)*	17.7 ± 4.6	17.0 ± 4.9	0.650
Current medications during follow-up			—
Pain medication during ≥1 follow-up	30 (96.8%)	27 (96.4%)	0.942
Duration of pain meds, d (mean ± SD)	8.2 ± 2.6	8.1 ± 2.8	0.861
Anticoagulants	0 (0.0%)	1 (3.6%)	0.475
Antibiotics	1 (3.2%)	0 (0.0%)	1.000
None	1 (3.2%)	1 (3.6%)	—
Chemotherapy or radiotherapy during follow-up†			0.130
Postmastectomy radiotherapy	0 (0.0%)	0 (0.0%)	—
Postmastectomy chemotherapy	0 (0.0%)	2 (7.1%)	—
Postmastectomy complication type	6 (19.4%)	7 (25.0%)	0.601
Ischemia	4 (12.9%)	4 (14.3%)	—
Hematoma	2 (6.5%)	0 (0.0%)	—
Seroma	0 (0.0%)	1 (3.6%)	—
Red breast syndrome	0 (0.0%)	1 (3.6%)	—
Infection/dehiscence	0 (0.0%)	0 (0.0%)	—
Capsular contracture	0 (0.0%)	0 (0.0%)	—
Other	0 (0.0%)	1 (3.6%)	—
No. complications resulting in surgical intervention	5 (83.3%)	4 (57.1%)	0.308
No. complications resulting in explantation	1 (16.7%)	1 (14.3%)	1.000

*Five patients were excluded from analysis (2 AlloDerm RTU and 3 SimpliDerm patients) who still had at least 1 drain remaining at 30 days follow-up.
†Fisher's Exact Test.

our knowledge, this is the first reporting of SimpliDerm use for immediate breast reconstruction.

SimpliDerm is derived from donated human dermis, which is gently processed using patented methods for decellularization and antigen removal before hydration and subsequent sterilization. The processing steps for SimpliDerm were designed to ensure low antigenicity and high sterility, while minimizing crosslinking and other alterations to ECM, thereby preserving the ECM microstructure and bioactive factors of native dermis. As demonstrated in a recent preclinical study, the intact ECM of SimpliDerm enhances and supports neovascularization, cell migration, tissue incorporation, and a modulated immune response that fosters remodeling of the hADM into native tissue.[15]

Like AlloDerm RTU, SimpliDerm is prehydrated and RTU, as opposed to freeze-dried. Studies comparing freeze-dried and RTU (ie, prehydrated) ADM have reported mixed findings regarding relative complication rates.[2,9,10,25,26] For example, several studies comparing freeze-dried AlloDerm with AlloDerm RTU reported significantly higher rates of infection, implant loss, and reoperation with the freeze-dried product.[2,26] However, other studies have reported comparable outcomes with freeze-dried and RTU ADM.[3,9,10,25,26] It is worth noting that the freeze-dried AlloDerm used in the studies noted above was an aseptically processed product that was not terminally sterilized, possibly accounting for these higher rates of infection. In contrast, the AlloDerm RTU used in the current study was terminally sterilized. However, the two hADM used in the current study are sterilized using different methods. SimpliDerm is terminally sterilized via gamma irradiation to a sterility assurance level of 10^{-6}, whereas AlloDerm RTU is sterilized via electron beam irradiation to a sterility assurance level of 10^{-3}.[27] Although researchers have noted that these processing methods do not seem to result in a difference in matrix stability, it is possible that the widely different sterility levels of these hADM could affect susceptibility to microbial colonization.[15] Further studies are warranted to evaluate the impacts of these and other aspects of processing on hADM clinical performance.

Table 4. Postoperative Adverse Events (AEs) among Patients with AEs (N = 13)

Adverse Event	AlloDerm RTU (n = 6; 46.2%)	SimpliDerm (n = 7; 53.8%)	*P*
AE seriousness			—
Serious	0 (0.0%)	0 (0.0%)	—
Not serious	6 (100.0%)	7 (100.0%)	—
AE intensity			0.416
Mild	2 (33.3%)	1 (14.3%)	—
Moderate	4 (66.7%)	6 (85.7%)	—
Severe	0 (0.0%)	0 (0.0%)	—
AE type			0.292
Infection	0 (0.0%)	1 (14.3%)	—
Flap ischemia	4 (66.7%)	4 (57.1%)	—
Hematoma	2 (33.3%)	0 (0.0%)	—
Seroma	0 (0.0%)	1 (14.3%)	—
Small skin pinhole with surrounding redness	0 (0.0%)	1 (14.3%)	—
Action taken			0.358
Medication	2 (33.3%)	2 (28.6%)	—
Procedure	2 (33.3%)	5 (71.4%)	—
None	1 (16.7%)	0 (0.0%)	—
Other	1 (16.7%)	0 (0.0%)	—

†A serious adverse event was defined as an event that: (1) threatened life, (2) resulted in permanent impairment of a body function or permanent damage to a body structure, (3) necessitated medical or surgical intervention to preclude such impairment, (4) required or prolonged hospitalization, or (5) was fatal.

Both SimpliDerm and AlloDerm RTU are commercially available in perforated and nonperforated formats in a variety of comparable sizes and thicknesses to support the full spectrum of soft tissue repair applications. For a commonly used size of 16 cm × 20 cm, our facility contracted cost of nonperforated SimpliDerm is $8770 and the cost for the same size of nonperforated AlloDerm RTU is $8877.

The preference for prepectoral reconstructions in this study reflects a growing trend to use this plane of implant placement when implants are placed in conjunction with ADM.[28] Initial evidence suggests that ADM-supported prepectoral reconstructions may be associated with less pain, reduced impact on range of motion, higher initial tissue expander fill volumes, improved aesthetic outcomes, and less capsular contracture compared with submuscular reconstructions.[5,28] In this study, the ease of use and efficacy of the prepectoral approach is supported, with adverse events similar to those reported in previous prepectoral studies.[2–9]

Further, the findings of this study suggest that SimpliDerm is associated with short-term adverse event profiles and rates that are comparable to those of AlloDerm and other ADMs in immediate breast reconstruction.[2–9] Adverse events were reported in 22% of subjects (19.4% AlloDerm RTU, 25% SimpliDerm), all of which were considered mild or moderate in intensity. In both groups in this study, the overall rates of complications aligned with rates previously reported in the literature (3.9%–33.5%), and the rate of infection in this study compares favorably with rates reported in the ADM comparative literature (0.2%–23.8%).[2–9,29,30]

One patient in each group (16.7% AlloDerm RTU, 14.3% SimpliDerm) underwent unplanned hADM explantation, a reasonable frequency compared with rates reported in the literature. One recent meta-analysis of ADM-assisted breast reconstructions identified rates of ADM explantation for any reason ranging from 1.3%–23.8%.[30] However, the small size of this case series suggests that the true rate of explantation and any associated risk factors will remain uncertain until greater patient experience is obtained.

Because studies have identified prolonged drain use as an independent risk factor for infection, factors that shorten time to drain removal are of clinical importance.[31] Factors significantly associated with longer time to drain removal following breast reconstruction reported in the literature include older patient age, larger expander size, high body mass index, neoadjuvant chemotherapy, and greater initial expander volume.[32–35] The impact of ADM on time to drain removal remains unclear, although some ADM studies have demonstrated variation in time to drain removal.[18,32,34–37] Other groups have demonstrated significant differences in seroma formation associated with differently processed ADM, further suggesting that ADM characteristics may influence fluid accumulation in the clinical setting.[38] In this initial study, there was no statistical differences between cohorts in infection rate, seroma rate, or time to drain removal. However, additional studies are warranted to explore potential differences in these outcomes between the two ADMs reported in this study.

LIMITATIONS

This study is limited by its sample size, duration of follow-up, retrospective design, and reliance on cases from a single surgeon. Due to challenges inherent to the study of ADM in postmastectomy breast reconstruction, these weaknesses are common in published studies in this setting. Additional cases, longer follow-up, extent of mastectomy excision and axillary dissection, and combining results across additional sites and surgeons will strengthen the reliability of the findings. The single-surgeon design may offer some advantages in terms of comparing between groups, as the same surgeon implanted both types of ADM, possibly eliminating practice variations that could influence outcomes of this small study.

CONCLUSIONS

The majority of implant-based breast reconstructions now involve the use of ADMs, which allow for greater surgeon control over the implant pocket, greater initial fill volumes in two-stage reconstructions, improved cosmesis, reduced risk for capsular contracture, and use of direct-to-implant reconstructions in select cases.[2–8] This report provides initial clinical evidence that SimpliDerm is a safe and effective option for soft-tissue support during two-stage breast reconstructions, with initial 30-day complication rates similar to those of AlloDerm RTU.

Brian P. Tierney, MD
Tierney Plastic & Reconstructive Surgery
2004 Hayes Street #315
Nashville, TN 37203
E-mail: tierneyplasticsurgery@hotmail.com

ACKNOWLEDGMENT

The author thanks Joshua Kilbridge (Kilbridge Associates) for his medical writing and editorial expertise.

REFERENCES

1. American Society of Plastic Surgeons. 2018 Plastic surgery statistics report. Available at https://www.plasticsurgery.org/documents/News/Statistics/2018/plastic-surgery-statistics-full-report-2018.pdf. Published 2019. Accessed December 12, 2020.
2. Parikh RP, Brown GM, Sharma K, et al. Immediate implant-based breast reconstruction with acellular dermal matrix: a comparison of sterile and aseptic alloderm in 2039 consecutive cases. *Plast Reconstr Surg.* 2018;142:1401–1409.
3. Gabriel A, Maxwell GP. AlloDerm RTU integration and clinical outcomes when used for reconstructive breast surgery. *Plast Reconstr Surg Glob Open.* 2018;6:e1744.
4. Zenn MR, Salzberg CA. A direct comparison of alloderm-Ready to Use (RTU) and DermACELL in immediate breast implant reconstruction. *Eplasty.* 2016;16:e23.
5. Margulies IG, Salzberg CA. The use of acellular dermal matrix in breast reconstruction: evolution of techniques over 2 decades. *Gland Surg.* 2019;8:3–10.
6. Vardanian AJ, Clayton JL, Roostaeian J, et al. Comparison of implant-based immediate breast reconstruction with and without acellular dermal matrix. *Plast Reconstr Surg.* 2011;128:403e–410e.
7. Forsberg CG, Kelly DA, Wood BC, et al. Aesthetic outcomes of acellular dermal matrix in tissue expander/implant-based breast reconstruction. *Ann Plast Surg.* 2014;72:S116–S120.
8. Salzberg CA, Ashikari AY, Koch RM, et al. An 8-year experience of direct-to-implant immediate breast reconstruction using human acellular dermal matrix (AlloDerm). *Plast Reconstr Surg.* 2011;127:514–524.
9. Lee KT, Mun GH. A meta-analysis of studies comparing outcomes of diverse acellular dermal matrices for implant-based breast reconstruction. *Ann Plast Surg.* 2017;79:115–123.
10. Mendenhall SD, Anderson LA, Ying J, et al. The BREASTrial Stage II: ADM breast reconstruction outcomes from definitive reconstruction to 3 months postoperative. *Plast Reconstr Surg Glob Open.* 2017;5:e1209.
11. Connor J, McQuillan D, Sandor M, et al. Retention of structural and biochemical integrity in a biological mesh supports tissue remodeling in a primate abdominal wall model. *Regen Med.* 2009;4:185–195.
12. Nilsen TJ, Dasgupta A, Huang YC, et al. Do processing methods make a difference in acellular dermal matrix properties? *Aesthet Surg J.* 2016;36(suppl 2):S7–S22.
13. Keane TJ, Badylak SF. The host response to allogeneic and xenogeneic biological scaffold materials. *J Tissue Eng Regen Med.* 2015;9:504–511.
14. Reing JE, Brown BN, Daly KA, et al. The effects of processing methods upon mechanical and biologic properties of porcine dermal extracellular matrix scaffolds. *Biomaterials.* 2010;31:8626–8633.
15. Ji H, Sukarto A, Deegan D, et al. Characterization of inflammatory and fibrotic aspects of tissue remodeling of acellular dermal matrix in a nonhuman primate model. *Plast Reconstr Surg Glob Open.* 2021;9:e3420.
16. Woo KJ, Park JW, Mun GH, et al. Does the use of acellular dermal matrix increase postoperative complications of the first-stage reconstruction of immediate expander-implant breast reconstruction: a Matched Cohort Study. *Ann Plast Surg.* 2017;79:341–345.
17. Wagner RD, Braun TL, Zhu H, et al. A systematic review of complications in prepectoral breast reconstruction. *J Plast Reconstr Aesthet Surg.* 2019;72:1051–1059.
18. Chang EI, Liu J. Prospective unbiased experience with three acellular dermal matrices in breast reconstruction. *J Surg Oncol.* 2017;116:365–370.
19. Hinchcliff KM, Orbay H, Busse BK, et al. Comparison of two cadaveric acellular dermal matrices for immediate breast reconstruction: a prospective randomized trial. *J Plast Reconstr Aesthet Surg.* 2017;70:568–576.
20. Ricci JA, Treiser MD, Tao R, et al. Predictors of Complications and Comparison of Outcomes Using SurgiMend Fetal Bovine and AlloDerm Human Cadaveric Acellular Dermal Matrices in Implant-Based Breast Reconstruction. *Plast Reconstr Surg.* 2016;138:583e–591e.
21. Stein MJ, Arnaout A, Lichtenstein JB, et al. A comparison of patient-reported outcomes between Alloderm and Dermacell in immediate alloplastic breast reconstruction: A randomized control trial. *J Plast Reconstr Aesthet Surg.* 2021;74:41–47.
22. Liu DZ, Mathes DW, Neligan PC, et al. Comparison of outcomes using AlloDerm versus FlexHD for implant-based breast reconstruction. *Ann Plast Surg.* 2014;72:503–507.
23. Sobti N, Liao EC. Surgeon-controlled study and meta-analysis comparing FlexHD and AlloDerm in immediate breast reconstruction outcomes. *Plast Reconstr Surg.* 2016;138:959–967.
24. Greig H, Roller J, Ziaziaris W, et al. A retrospective review of breast reconstruction outcomes comparing AlloDerm and DermaCELL. *JPRAS Open.* 2019;22:19–26.
25. Macarios D, Griffin L, Chatterjee A, et al. A meta-analysis assessing postsurgical outcomes between aseptic and sterile alloderm regenerative tissue matrix. *Plast Reconstr Surg Glob Open.* 2015;3:e409.
26. Hanson SE, Meaike JD, Selber JC, et al. Aseptic freeze-dried versus sterile wet-packaged human cadaveric acellular dermal matrix in immediate tissue expander breast reconstruction: a propensity score analysis. *Plast Reconstr Surg.* 2018;141:624e–632e.
27. AlloDerm Select Regenerative Tissue Matrix. *Instructions for Use.* Branchburg, NJ: Allergan; 2020.
28. Teoh V, Gui G. Direct to implant breast reconstruction with biological acellular dermal matrices. *Br J Hosp Med (Lond).* 2020;81:1–7.
29. Newman MI, Swartz KA, Samson MC, et al. The true incidence of near-term postoperative complications in prosthetic breast reconstruction utilizing human acellular dermal matrices: a meta-analysis. *Aesthetic Plast Surg.* 2011;35:100–106.
30. Loo YL, Kamalathevan P, Ooi PS, et al. Comparing the outcome of different biologically derived acellular dermal matrices in implant-based immediate breast reconstruction: a meta-analysis of the literatures. *Plast Reconstr Surg Glob Open.* 2018;6:e1701.
31. Hanna KR, Tilt A, Holland M, et al. Reducing infectious complications in implant based breast reconstruction: impact of early expansion and prolonged drain use. *Ann Plast Surg.* 2016;76(suppl 4):S312–S315.
32. Woo KJ, Paik JM, Mun GH, et al. Analysis of factors influencing drain amount, time to drain removal, and seroma formation in patients undergoing immediate expander-implant breast reconstruction. *J Plast Surg Hand Surg.* 2018;52:53–59.
33. Tokiyoshi T, Tsunashima C, Nomura T, et al. Factors preventing prolonged closed-suction drain placement after immediate breast reconstruction with tissue expanders. *Kobe J Med Sci.* 2020;65:E132–E137.
34. Lee KT, Hong SH, Jeon BJ, et al. Predictors for prolonged drainage following tissue expander-based breast reconstruction. *Plast Reconstr Surg.* 2019;144:9e–17e.
35. Lim YM, Lew DH, Roh TS, et al. Analysis of factors that affect drainage volume after expander-based breast reconstruction. *Arch Plast Surg.* 2020;47:33–41.
36. Israeli Ben-Noon H, Farber N, Weissman O, et al. The effect of acellular dermal matrix on drain secretions after immediate prosthetic breast reconstruction. *J Plast Surg Hand Surg.* 2013;47:308–312.
37. Pittman TA, Fan KL, Knapp A, et al. Comparison of different acellular dermal matrices in breast reconstruction: the 50/50 Study. *Plast Reconstr Surg.* 2017;139:521–528.
38. Michelotti BF, Brooke S, Mesa J, et al. Analysis of clinically significant seroma formation in breast reconstruction using acellular dermal grafts. *Ann Plast Surg.* 2013;71:274–277.