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RESEARCH ARTICLE

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Prospective unbiased experience with three acellular dermal matrices in breast reconstruction

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Background: The use of acellular dermal matrix (ADM) has become the standard of care in breast reconstruction. However, the majority of current studies are biased or combine large databases introducing inherent flaws. Here, we present a prospective single surgeon experience comparing three ADM.

Methods: All expander based breast reconstructions between 2014 and 2015 using ADM were included.

Results: Eighteen patients (32 breasts) underwent reconstruction using Flex Pliable, 15 patients (22 breasts) used Alloderm, and 14 patients (20 breasts) had Dermacell. There were no significant differences in patient demographics or comorbidities. All expanders were placed into a subpectoral position, and there were no direct to implant cases. Average intraoperative fill was comparable, (Flex: 225 cc, Alloderm: 180 cc, Dermacell: 130 cc). There were no differences in seroma, infection, or mastectomy skin flap necrosis rates. There were no cases of red breast, expander explanation or failed reconstruction in any cohort. Time to drain removal was significantly shorter in Flex and Dermacell patients compared to Alloderm (20 days vs 15 days vs 26 days, respectively; $P = 0.01$).

Conclusions: While there are differences between available ADM, successful outcomes can be achieved with proper patient selection, sound surgical technique, and diligent post-operative management.

KEYWORDS
acelluar dermal matrix, alloderm, breast reconstruction, dermacell, flex pliable

1 | INTRODUCTION

The use of acellular dermal matrix (ADM) has become an integral component in prosthesis based breast reconstruction.[1,2] Since its introduction, the utilization of these products has grown rapidly such that new products are regularly introduced to the market. Reported benefits of ADM include improved soft tissue coverage of the lower pole, higher intraoperative fill volumes, crisper definition of the inframammary fold, and superior cosmetic outcomes.[3–5] Further, some studies have also reported improved cosmetic outcomes and correcting complications like capsular contractures thereby justifying the cost of these products.[6,7] In particular, with the growing popularity and high success rates with direct-to-implant and pre-pectoral tissue expander placement, incorporation of ADM is often a requirement to maximize outcomes.[8–10]

However, despite the reported benefits, the costs of ADM need to be considered in the changing era of healthcare and its utilization should be selective.[11–13] There are also large studies reporting increased complication rates with the use of these products in addition to the increased costs of the ADM. Increased risks of seroma, infection, and explanation have all been reported with the use of these products.[14–18] While many large studies have demonstrated significant complications, many reconstructive plastic surgeons have achieved and reported excellent outcomes with low complication rates.[19–22] Unfortunately, many studies in the literature are biased due to industry involvement and payments from companies who manufacture these products.[23,24] Regardless of the possibility of conflicts of interest, the factors that likely cannot be conveyed in many studies are surgeon experience and technique. These factors are marginalized when pooling patients from an institution or multiple institutions as the details of surgical technique that are critical to successful outcomes are lost. Details such as choice of ADM, ADM preparation, intraoperative expander fill, drain management, post-operative antibiotics, and the fine nuances of the reconstruction and post-operative management are not accounted and vary tremendously from surgeon to surgeon.

Consequently, the reconstructive surgeon needs to utilize judgment and experience in deciding whether to incorporate ADM into one's practice. The aim of the present study was to present a single surgeon's unbiased prospective experience comparing three ADM products in subpectoral two-stage expander breast reconstruction. To our knowledge, this is the first study examining outcomes using Flex Pliable (F), Alloderm (A), and Dermacell (D) in breast reconstruction and the first to compare the three ADM in breast reconstruction in a prospective unbiased fashion.

2 | METHODS

All patients undergoing two-stage breast reconstruction with placement of expanders and supplementation of the inferior pole with ADM were included after institutional review board approval. The three ADM products included were Alloderm (Acellity Inc., Branchburg, NJ), Flex Pliable (MTF, Edison, NJ), and Dermacell (Lifenet Health, Virginia Beach, VA). The study was not performed in a randomized fashion; however, there was no selection bias in the choice of which ADM was used for each patient. The ADM used was based on the time when the reconstruction was performed and when each ADM became available for use at our institution. Alloderm was used from January 2014 to August 2014, while Flex Pliable was used from August 2014 to May 2015, and Dermacell from May 2015 to February 2016. Patients were followed prospectively on a regular basis until completion of their reconstruction with either exchange of the expander to a permanent implant or with autologous tissue. All complications including hematoma, infection, readmission, reoperation, explantation, or loss of the reconstruction were recorded. Patients undergoing reconstruction using total muscle coverage or prepectoral placement were excluded from the study.

3 | SURGICAL TECHNIQUE AND MANAGEMENT

All operations were performed in an identical fashion. Briefly, following completion of the mastectomy, the pectoralis major muscle was inspected. If the pectoralis major muscle inserted at the level of the inframammary fold or if adequate serratus fascia was present, then the reconstruction was performed without ADM. Patients who received total muscle coverage were excluded from the study. All expanders were handled after changing gloves and washed with antibiotic irrigation consisting of bacitracin and polymyxin prior to implantation. All expanders were placed into a subpectoral position. The pectoralis major muscle was elevated to the level of the clavicle and released from its insertion. An 8 × 16 cm piece of ADM was used for all cases to eliminate the impact of size of ADM on outcomes. The ADM was opened directly into the antibiotic irrigation (bacitracin and polymyxin) for 10 min and then rinsed with normal saline prior to implantation and only handled by the reconstructive surgeon. All ADM were inset as an inferior sling using monofilament sutures at the level of the inframammary fold after the fold was reinset using monofilament sutures. Gloves were changed prior to handling the expanders, and the expanders were rinsed in the same antibiotic irrigation prior to placement. The wound was dressed with an Ioban drape (3 M, St. Paul, MN) followed by new surgical towels. Intraoperative fill was based on the volume necessary to allow tension free closure of the skin. No cases employed intraoperative indocyanine green angiography. After placement of the expander, the pectoralis muscle was secured to the ADM using monofilament suture in a pants-over-vest fashion. The pocket was again irrigated with antibiotic irrigation prior to closure. All patients received two closed suction drains with one drain in the subpectoral space and one in the subcutaneous space. The skin was closed with monofilament sutures and dressed with mupirocin ointment and xeroform gauze.

Patients were admitted overnight and maintained on intravenous antibiotics until discharge. Drain management was identical in all patients. Drains were left in place until the volume decreased to less than 30 cc over 24 h for 2 consecutive days. Patients were maintained on oral antibiotics (Duricef, or Bactrim if patients had a penicillin allergy, and clindamycin if patients had allergies to penicillin and sulfa drugs) while drains were in place. Expansion was started 10-14 days following surgery and was continued until patients achieved the size they desired.

4 | STATISTICAL ANALYSIS

Descriptive statistics including means, medians, standard deviations, and ranges were used to summarize the continuous variables such as age, BMI, and days of drains. Frequency counts and percentages were used to summarize the categorical variables. Chi-square or fisher exact tests were used to evaluate the association between two categorical variables. Kruskal-Wallis test was used to compare if the difference in continuous variables among three patient groups. All tests were two-sided. A P value of <0.05 was considered significant. The analyses were performed in SAS 9.3(SAS Institute Inc., Cary, NC) and R (The R Foundation for Statistical Computing). A senior staff biostatistician (JL) performed all statistical analyses.

5 | RESULTS

5.1 | Patients

Overall, 47 patients (74 breasts) underwent ADM supplemented expander breast reconstruction (mean age: 48.9 years and mean BMI: 25.2 kg/m^2) with 18 patients receiving Flex Pliable (32 breasts), 15 patients receiving Alloderm (22 breasts), and 14 patients using Dermacell (20 breasts). Patient demographics were comparable in the three cohorts (average age: F: 47.6 years vs A: 47.5 years vs D: 54.1 years). Average BMI was also comparable between groups (F: 24.9 kg/m^2 vs A: 25.7 kg/m^2 vs D: 25.7 kg/m^2). Four Flex patients had nipple-sparing mastectomies, while two Alloderm patients and no Dermacell patients had nipple-sparing mastectomies. There were no cases of nipple necrosis in these patients. Intraoperative fill was

TABLE 1 Patient demographics in each ADM cohort

	ADM						
	Flex		AlloDerm		Dermacell		
	N	%	*N*	%	*N*	%	*P*-value
BRA categories							
A/B/C	15	83.33	9	60.00	9	75.00	
D+	3	16.67	6	40.00	3	25.00	0.34
Smoke	15	83.33	15	100.00	11	91.67	
No							
Yes	3	16.67	–	–	1	8.33	0.29
XRT							
No	12	66.67	12	80.00	7	58.33	
Yes	6	33.33	3	20.00	4	33.33	0.65
Neoadjuvant chemo							
No	15	83.33	13	86.67	7	58.33	
Yes	3	16.67	2	13.33	5	41.67	0.23
Chemo							
No	14	77.78	11	73.33	9	75.00	
Yes	4	22.22	4	26.67	3	25.00	>0.99

comparable between the three groups (F: 225 cc vs A: 180 cc vs D: 130 cc; $P > 0.05$). Similarly, there was no significant difference in patients who underwent post-operative radiation or had chemotherapy between the cohorts (Table 1). Thirty-two patients proceeded to the secondary stage with definitive reconstruction using an implant while 12 patients proceeded to an autologous free flap reconstruction. Three patients underwent reconstruction using an implant with a pedicle latissimus dorsi myocutaneous flap. The mean time to drain removal was 20 days in patients receiving Flex Pliable versus 26 days in Alloderm patients and 15 days in Dermacell patients ($P = 0.025$) when the drain output satisfied removal criteria.

In order to control for trimming of the rectangular sheets, analysis performed based on square centimeters. Alloderm was the most expensive of the three ADM (set as the reference) compared to Flex Pliable (91.5%) and Dermacell (83.2%). However, in the setting of a bilateral breast reconstruction, MTF offers a breast kit containing two matched pieces of Flex Pliable which is priced even lower than the comparable sheet of Alloderm (80.7%). For surgeons who prefer to use the large contoured Alloderm (not used in present study), the difference in pricing persisted with greater cost savings when compared to the 8 × 16 pieces of the other two ADM (Flex Pliable: 88.9% and Dermacell: 80.8%).

5.2 | Complications

All patients were admitted overnight and discharged the following day with oral antibiotics and seen 10-14 days following surgery, and then weekly for expansion until the patient achieved the size she desired. All complications were noted including seroma, hematoma, cellulitis or red breast, infection, mastectomy skin flap necrosis, or wound dehiscence. No patients in any cohort underwent a reoperation for washout of an infection or removal of the expander or ADM. There were no patients who lost the expander or their reconstruction in any cohort. One patient in the Flex Pliable and Alloderm group underwent aspiration or drain placement for a seroma following drain removal. The remaining complications for all three cohorts are shown in Table 2.

TABLE 2 Complications following ADM placement

	Flex pliable *n* = 32	Alloderm *n* = 22	Dermacell *n* = 18	*P*-value
Mastectomy skin flap necrosis	2	1	0	0.77
Hematoma	1	0	0	>0.99
Seroma	1	1	0	0.73
Red breast	0	0	0	n/a
Cellulitis/ infection	0	0	0	n/a
Washout/ debridement	0	0	0	n/a
Wound dehiscence	0	0	1	>0.99
Explantation	0	0	0	n/a

5.3 | Cost analysis

Cost analysis of the three different acellular dermal matrices demonstrated differences in pricing despite using an 8 × 16 cm piece in all cases.

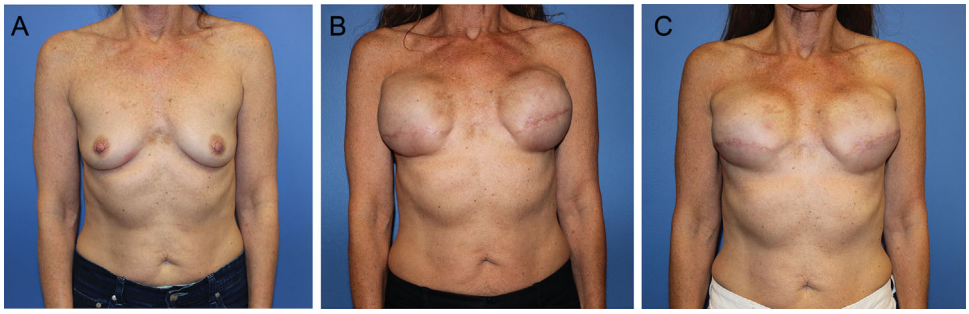

FIGURE 1 A) Patient presents for bilateral skin-sparing mastectomies following diagnosis of a right breast ductal carcinoma in situ. B) The patient proceeds with bilateral tissue expander placement with Alloderm coverage of the lower pole and C) subsequent exchange of both expanders with permanent silicone implants

5.4 | Follow-up

Average follow-up was 15.0 months (range: 10.1-33.3 months). At the time of exchange for a permanent implant or free flap reconstruction, all grafts were noted to have completely incorporated into the mastectomy skin flaps. Following definitive reconstruction, no patients developed delayed seromas, infections, or other complications requiring removal of the ADM. Representative photos of patients who have completed their reconstruction with Alloderm (Fig. 1), Flex Pliable (Fig. 2), and Dermacell (Fig. 3) are presented.

6 | DISCUSSION

The use of ADM is becoming an integral part of prosthesis based breast reconstruction and also plays a pivotal role in secondary revisions in breast reconstruction. Since their introduction, plastic surgeons are utilizing them more and more, and as such new products are emerging on the market regularly.[1–3] Given the myriad of ADM available, the reconstructive surgeon must decide which product, if any, to use to achieve the safest, most optimal outcomes for their patients. A number of studies have aimed to determine which of the ADM have the lowest risk profile to decipher whether one product is indeed superior to others.[25–27] Unfortunately, many studies are biased due to conflicts of interest, and large studies compiling the patients from multiple surgeons and institutions dilute the fine nuances of surgeon technique and experience in achieving the best outcomes.

While the current study has significant limitations, the greatest being the small sample size, the study is unique compared to many other studies in the literature. Such studies often compile the results of multiple surgeons and even from multiple institutions in order to achieve larger numbers. As all surgeons realize, many technical factors are critical to achieving successful outcomes. With a single surgeon experience, using the exact same surgical technique and management, other confounding factors are controlled allowing for a more focal analysis of the ADM alone. An additional strength of this study is the lack of industry involvement which eliminates the potential for bias in the results presented. The present study is not meant to discredit other studies which are also valid, but the present study aims to present an objective analysis of three prominent ADM on the market, Flex Pliable, Alloderm, and Dermacell. Just as each product has its merits, reconstructive surgeons will continue to explore the benefits and risks of each one to aid in deciphering which products are superior to others.

Despite the small number of patients and respective breasts included in the study, this is the first prospective study comparing Flex Pliable, Alloderm, and Dermacell demonstrating equivalent outcomes between the three products except that Alloderm appears to have the longest time to drain removal. This should be considered when determining the optimal time for drain removal as all reconstructive surgeons are aware that a seroma can precipitate infection and loss of

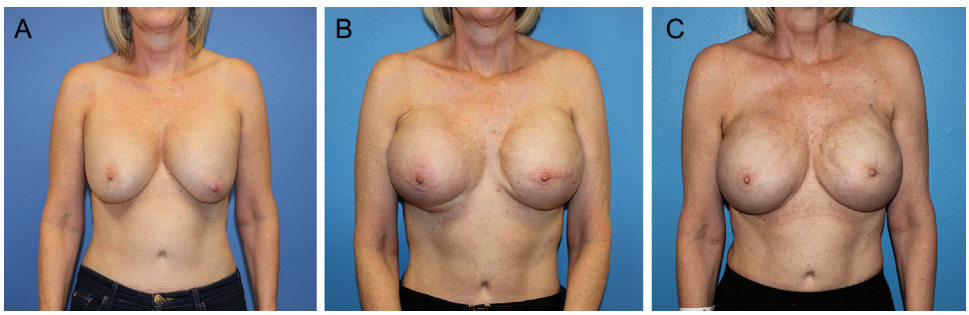

FIGURE 2 A) Patient with a left side breast cancer presents for bilateral nipple-sparing mastectomies and has had prior breast augmentation with subpectoral saline implants. B) Patient undergoes replacement of her prior implants with tissue expanders and supplementation of the inferior pole with Flex Pliable. C) Post-operative photos following exchange of the expanders with permanent silicone implants

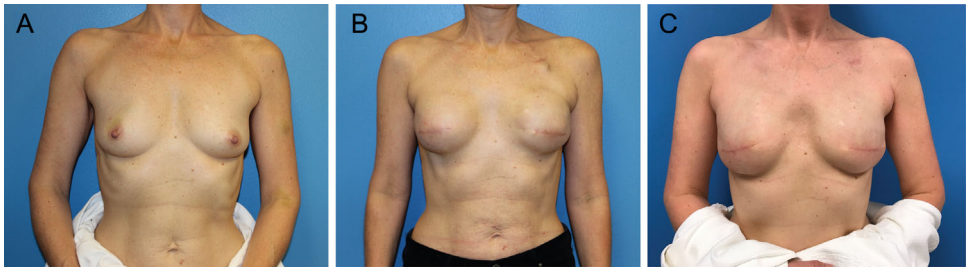

FIGURE 3 A) Patient presents for bilateral skin-sparing mastectomies for a right-sided breast cancer. B) Post-operative photos following placement of bilateral subpectoral expanders with Dermacell. C) Final post-operative result following exchange of the expanders for her permanent silicone implants

the expander. Further, the impact on patient quality of life should be considered as well, given the greatest complaint of patients undergoing tissue expander breast reconstruction is the presence of drains. Prior studies comparing FlexHD have reported superior outcomes with Alloderm[27]; however, the newer formulation of the Musculoskeletal Transplant Foundation (MTF) product, Flex Pliable, has not been thoroughly investigated. To our knowledge, there are no studies specifically examining Flex Pliable in breast reconstruction, and no unbiased studies examining the use of Dermacell in breast reconstruction.[27,28] Finally, in the changing era of healthcare, costs must also be considered carefully with the use of these products. Our analysis demonstrates there are marked differences in pricing between the three ADM with Alloderm being the most expensive of the three products. This will be of even greater consideration with the increasing prevalence of contralateral prophylactic mastectomies and the anticipation of reconstruction bilateral mastectomy defects.[29,30]

The decision to proceed with a prosthesis-based reconstruction versus a free flap is often based on a number of factors predominantly patient desires and surgeon comfort and preferences. However, for most reconstructive surgeons, the use autologous tissue is preferred for patients with more advanced disease who will receive or have received radiation. Similarly for patients who have undergone a modified radical mastectomy where the skin has not been preserved, the use of autologous tissue is recommended. However, for most patients in the modern era who receive skin-sparing or even nipple-sparing mastectomies, the use of an expander remains the most commonly performed technique. Based on the current study, radiation did not increase the risk of complications; however, the reconstructive surgeon needs to consider the risks of using ADM which may lead to complications that can potentially delay adjuvant therapies. Once patients have completed their radiation and adjuvant therapies, the definitive reconstruction should be performed a minimum of 6 months to a year following completion of radiation.[31,32]

Ultimately, while ADM has been associated with increased risks of complications, the more critical factors in minimizing complications lies with the operating surgeon to use judgment and experience to guide patient selection and operative technique. In patients with comorbidities including obesity, smoking, prior radiation, and poor mastectomy skin flaps, limited use of ADM should be considered. Intraoperative fill can also have a significant role in complications and judicious filling of the expander can likely decrease the risks of complications in expander-implant reconstruction.[18] The use of intraoperative indocyanine green (ICG) imaging is also gaining in popularity and may be useful in determining the optimal intraoperative fill volume.[33,34] Ultimately, regardless of the studies published in the literature that are all independently valid in their own capacity, novel technologies, including ADM, can be used effectively and safely in the hands of competent, safe, and judicious reconstructive plastic surgeons.

7 | CONCLUSIONS

Flex Pliable, Alloderm, and Dermacell can be used with equivalent success rates; however, the time to drain removal and cost favor certain ADM over others. The use of ADM in expander-implant breast reconstruction should be selective, and successful outcomes are more dependent on proper patient selection, surgical technique, and appropriate post-operative management than the type of ADM.

DISCLOSURES

The author has no commercial associations or financial disclosures that might pose or create a conflict of interest with information presented in this manuscript at the time of the study. No funding was received for the work presented in this manuscript.

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SYNOPSIS

The use of acelluar dermal matrices is becoming the standard of care in expander implant breast reconstruction; however, the majority of studies examining differences in ADM are biased with industry involvement while large volume studies are confounded by differences in technique and management. As such, there is need for uniform, unbiased studies examining the use of ADM in prosthesis based breast reconstruction.