

ORIGINAL ARTICLE

Evaluation of Xenograft Efficacy in Immediate Prosthesis-based Breast Reconstruction

Nikhil Sobti, MD Neel Vishwanath, BS Victor A. King, MD Vinay Rao, MD, MPH Ben Rhee, BA Carole S.L. Spake, MSc Mimi R. Borrelli, MD Ronald A. Akiki, MD Karl H. Breuing, MD

Background: The advent of acellular dermal matrix (ADM) has revolutionized prosthesis-based breast reconstruction. However, paucity of human cadaveric tissue has resulted in limitation of supply and increased associated costs, prompting concerted effort to identify xenograft alternatives. Although studies have examined the safety of Artia, a porcine-derived ADM, few have evaluated its clinical efficacy as soft tissue reinforcement. This study uniquely evaluates the clinical efficacy of Artia in implant-based breast reconstruction.

Methods: IRB-approved retrospective chart review was conducted to identify 243 consecutive TE-based procedures performed at a tertiary academic medical center between March 2017 and March 2021. Propensity matching was conducted to minimize differences between cohorts. Efficacy metrics, defined as initial tissue expander (TE) fill volume, number of TE fills, and time interval between exchange of TE for final implant, were compared between xenograft (Artia) and allograft (AlloDerm) groups.

Results: Patients who underwent Artia-based breast reconstruction achieved superior initial TE fill volume relative to those who underwent AlloDerm-based breast reconstruction via univariate analysis $(317.3 \pm 185.8 \text{ mL} \text{ versus } 286.1 \pm 140.4 \text{ mL}, P < 0.01)$ when patient and operative characteristics were well-matched. However, linear regression analysis failed to demonstrate difference in efficacy metrics, such as initial TE fill volume (*P* = 0.31), ratio between initial TE fill volume and final implant size (*P* = 0.19), and number of TE fills (*P* = 0.76). Complication rates were comparable between groups.

Conclusion: This study suggests that Artia can be used as a safe and efficacious alternative to human-derived ADM in immediate TE-based breast reconstruction. (*Plast Reconstr Surg Glob Open 2022;10:e4534; doi: 10.1097/GOX.00000000004534; Published online 28 September 2022.*)

INTRODUCTION

The advent of acellular dermal matrix (ADM), a decellularized cadaveric soft tissue graft, has revolutionized prosthesis-based breast reconstruction, conferring soft tissue reinforcement to the mastectomy skin flap, thereby decreasing rates of delayed wound healing, tissue necrosis, and prosthesis loss.^{1,2} As such, ADM has allowed for placement of tissue expanders (TE) with higher initial fill volume in staged reconstructive procedures and has

From the Division of Plastic and Reconstructive Surgery, The Warren Alpert Medical School of Brown University, Providence, RI. Received for publication May 18, 2022; accepted July 18, 2022. Sobti and Vishwanath have contributed equally to this work. 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.00000000004534 facilitated the transition toward direct-to-implant (DTI) breast reconstruction. $^{\rm 3,4}$

Despite the utility of ADM within prosthesis-based breast reconstruction, paucity of cadaveric tissue has resulted in limitation of supply and increased associated costs.^{5–7} With widespread adoption of surgical adjuncts for breast reconstruction, there has been concerted effort to identify alternatives to ADM to minimize costs to the patient and institution, while maintaining adequate soft tissue support.^{8–10} The use of synthetic mesh material (such as Vicryl) has been explored; however, rapid hydrolysis has limited the efficacy of soft tissue reinforcement, thereby reducing the maximum initial fill volume for TE or frequency of DTI reconstruction.^{4,11–13} Attention has, instead, turned to the use of xenografts, such as porcine

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or bovine-derived surgical adjuncts, which hold promise to increase unit supply and decrease procedural cost.

Artia, a porcine-derived ADM, is gaining popularity for use as soft tissue reinforcement in prosthesis-based breast reconstruction. Compared with other commercially available xenografts, such as Strattice, Artia reportedly produces a less robust inflammatory response to extracellular antigens, given novel processing techniques that include reliable antigen removal and terminal sterilization.¹⁴ In addition, Artia has proven to be more pliable and consistent in sheet thickness than its counterparts, thereby facilitating intraoperative placement and implant coverage.

Although previous studies have been conducted investigating the safety of Artia, there are no studies evaluating the efficacy of xenograft surgical adjuncts in immediate prosthesis-based breast reconstruction.14,15 The goal of this study was to examine clinical efficacy of Artia in prosthetic breast reconstruction when compared with human cadaveric ADM (AlloDerm). Objective endpoints of efficacy have been previously defined and validated, using initial TE fill as the primary endpoint to represent soft tissue reinforcement to the mastectomy skin flap conferred by surgical adjunct.⁴ Herein, we compared postoperative outcomes following immediate staged breast reconstruction between Artia and Alloderm groups. We hypothesize that Artia use in alloplastic breast reconstruction will be associated with comparable initial TE fill volumes, thereby demonstrating a similar efficacy profile.

METHODS

Study Design and Population

A retrospective chart review was performed to identify patients who underwent immediate or delayed TE placement following mastectomy between March 2017 and March 2021 at a tertiary academic medical center. IRB approval was obtained with a waiver of informed consent for retrospective chart review. The Artia group included any patient who underwent TE placement with Artia used as an inferolateral sling for subpectoral breast reconstruction or to completely encase the prosthesis in prepectoral breast reconstruction. The human cadaveric ADM group was defined as any patient who underwent TE placement with AlloDerm in either the subpectoral or prepectoral plane. Those patients who underwent reconstruction with total or partial muscle coverage without surgical adjunct were excluded from the study.

Data Collection and Analysis

Patient demographic and characteristic data were recorded, including age at surgery, obesity (BMI >30), history of smoking, history of breast irradiation, laterality (bilateral versus unilateral), surgical adjunct use (xenograft versus allograft), initial TE fill volume, final implant size, number of TE fills, and interval between TE placement and TE-implant exchange. The following post-operative complications were identified: tissue necrosis (or delayed wound healing), hematoma, and surgical site infection. BMI was calculated as mass/meters squared (kg/m²).

Takeaways

Question: Does porcine-derived surgical adjunct, Artia, demonstrate similar clinical efficacy to the more commonly used, human-derived AlloDerm?

Findings: Propensity-matched retrospective cohort study of immediate tissue expander (TE) based-breast reconstructions, which demonstrated comparable efficacy profiles between Artia and AlloDerm with regard to initial TE fill, number of TE fills, and ratio of initial TE fill to final implant size.

Meaning: Artia is a safe and efficacious xenograft surgical adjunct for use in immediate prosthesis-based breast reconstruction and, therefore, offers a cost-effective alternative to traditional allograft materials for plastic and reconstructive surgeons

Statistical Analysis

Data were analyzed using SPSS 25 (IBM Corp., Armonk, N.Y.). Univariate analysis was conducted to compare patient characteristics between surgical adjunct groups. Pearson chi-square testing was used for categorical variables. A Shapiro-Wilk test was used to test for normality among continuous variables. Variables that were nonnormally distributed were analyzed using a Mann-Whitney test. The remaining continuous variables were compared using Student's t-test. Unadjusted logistic regression was used to analyze outcome data by patient and by breast, assuming that outcomes for each breast were independent events. A binomial logistic regression model was constructed to determine the relationship between adjunct type and postoperative complication by controlling for confounding variables (age, history of smoking, radiation treatment, plan of implant placement, and number of sheets of adjunct used). For each outcome, an odds ratio, 95% confidence interval, and P value were calculated. Linear regression modeling was performed to identify independent variables associated with initial tissue expander fill, number of TE fills, and time interval to implant exchange. Additionally, caliper-based propensity matching was performed to identify sub-groups with similar ages, body habitus, smoking and radiation history, and plane of implant placement, which are variables that may impact the initial fill volume at the index operation. Univariate, binomial regression, and linear regression analyses were performed between sub-groups to compare postoperative sequelae and efficacy endpoints between matched cohorts. Statistical significance was defined as a P value less than 0.05.

RESULTS

Patient Characteristics

Retrospective review identified 243 consecutive mastectomies followed by TE placement. A total of 160 (65.8%) breasts underwent allograft-based TE placement, whereas the remaining 83 experienced xenograft-based reconstruction. The timing of the reconstruction was immediate for all patients. Minimum follow-up was 6 months. The mean age of the women was 51.6 ± 11.2 years. Table 1 presents the clinical characteristics of the total cohort by surgical adjunct (allograft versus xenograft). Patient characteristics between the allograft and xenograft groups were well matched, without statistically significant variance in age, obesity, laterality, timing of reconstruction, and chemotherapy. However, patients in the xenograft group were more likely to have a history of radiotherapy or prepectoral implant placement. Differences in patient characteristics among cohorts were controlled for in binomial regression analysis.

Postoperative Outcomes

Mastectomy skin flap necrosis (n = 45, 18.5%) was the most common postoperative complication observed, followed by surgical site infection (n = 34, 14.0%) and seroma formation (n = 24, 9.9%). Postoperative complication rates were comparable between groups (Table 2). A binomial regression model was constructed to control for potential confounding variables, including age, history of smoking, breast irradiation, plane of reconstruction, and number of sheets of surgical adjunct used. Our analysis revealed that allograft use was a predictor of surgical site infection (OR, 3.44; 95% CI, 1.08–12.77, P = 0.05). There were no other significant differences in outcomes between allograft and xenograft groups (Table 3).

Evaluation of Efficacy Endpoints

Mean initial TE fill volume was significantly higher in the xenograft group when compared with the allograft cohort (341.5 \pm 189.5 mL versus 277.7 \pm 148.3 mL, P < 0.01). The final implant size achieved was greater in the allograft group (allograft, 567.9 \pm 147.1 versus xenograft, 492.9 \pm 140.0, P < 0.01). However, the ratio of initial TE fill volume compared with the final implant volume strongly favored the xenograft-assisted TE group (0.69 \pm 0.33 versus 0.46 \pm 0.18, P < 0.01). In addition, secondary efficacy endpoints were superior in the xenograft group, with significantly fewer fill visits (3.46 \pm 2.93 fills versus 5.16 \pm 2.99 fills, P < 0.01). Mean time interval to implant exchange (238.0 \pm 133.6 days versus 245.7 \pm 197.6 days, P = 0.99) was similar between groups (Table 4). Linear regression analysis was performed to account for potential confounders,

Table 1.	Patient	and O	perative	Charact	eristics
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including age, history of smoking, history of irradiation, plane of reconstruction, and number of sheets of surgical adjunct used. Significant differences were observed in ratio of initial TE fill volume compared with final implant volume (P < 0.01) and number of TE fills (P = 0.01), favoring the xenograft cohort (Table 5).

Propensity Matching

Caliper-based propensity matching was performed to identify xenograft and allograft sub-groups with similar patient characteristics (age at surgery, history of smoking, history of irradiation, and plane of reconstruction). Demographic and operative data are summarized in Table 6. Matched cohorts only differed in average number of sheets used, with higher utilization of Artia per reconstruction (1.5 \pm 0.50 sheets versus 1.2 \pm 0.36 sheets, P < 0.01). Whereas rates of tissue necrosis and hematoma were comparable via univariate analysis, surgical site infection remained more prevalent in the allograft cohort (7.7%) versus 20.0%, P = 0.04). Primary efficacy metrics were largely equivalent among groups, without statistically significant difference in initial fill volume and final implant size. Ratio of initial TE fill volume compared with final implant volume was superior in the xenograft group after propensity matching (Table 7). However, linear regression and binomial regression analyses failed to identify differences in safety or efficacy endpoints between cohorts (Tables 8 and 9).

DISCUSSION

The use of acellular dermal matrix as soft tissue reinforcement has marked a transition in the standard of care for prosthesis-based breast reconstruction, serving as a scaffold for increased TE fill volumes and facilitating the rise of direct-to-implant placement within recent years.^{16,17} The relative safety and efficacy of human-derived ADM, such as AlloDerm and FlexHD, have been previously established in various prospective and retrospective cohort studies.^{4,18–23} However, paucity of human cadaveric skin and high manufacturing costs have slowed the widespread adoption of human ADM worldwide and necessitated the search for structurally analogous xenograft adjuncts, such as Artia, for use in breast reconstruction.^{14,24} Although

Variable	Total (%)	Xenograft (%)	Allograft ($\%$)	Р
No. patients	158	53 (33.5)	105 (66.5)	
No. breasts	243	83 (34.2)	160 (65.8)	
No. unilateral	73 (30.9)	23 (43.4)	50 (47.6)	
No. bilateral	85 (69.1)	30 (56.6)	55 (52.4)	
Mean age \pm SD (yr)	51.6 ± 11.2	49.6 ± 11.7	52.6 ± 10.9	0.07
No. obeset	82 (33.7)	23 (27.7)	59 (36.9)	0.20
History of smoking	119 (49.0)	43 (51.8)	76 (47.5)	0.56
Radiation	74 (30.4)	33 (39.8)	41 (38.7)	0.88
Chemotherapy	137 (56.4)	45 (54.2)	92 (57.5)	0.20
Plane of reconstruction				< 0.01*
Prepectoral	135 (55.6)	61 (73.5)	74 (46.3)	
Subpectoral	108 (44.4)	22 (26.5)	86 (53.8)	
No. sheets used \pm SD	1.3 ± 0.49	1.6 ± 0.54	1.2 ± 0.38	<0.01*

*Statistically significant (P < 0.05).

†BMI > 30.

Table 2. Comparison of Safety Outcomes between Xenograft and Allograft Groups, by Breast

Outcome	Total	Xenograft (%)	Allograft (%)	Р
Tissue necrosis Infection Hematoma	$\begin{array}{c} 45 \ (18.5) \\ 34 \ (14.0) \\ 5 \ (2.1) \end{array}$	$\begin{array}{c} 17 \ (20.5) \\ 9 \ (10.8) \\ 1 \ (1.2) \end{array}$	$\begin{array}{c} 28 \ (17.5) \\ 25 \ (15.6) \\ 4 \ (2.5) \end{array}$	$\begin{array}{c} 0.57 \\ 0.31 \\ 0.66 \end{array}$

*Statistically significant (P < 0.05).

Table 3. Binomial Regression of Complication between Xenograft and Allograft Groups, by Breast

Covariate	Allograft versus Xenograft			
	OR (95%CI)	Р		
Tissue necrosis	0.43(0.17 - 1.08)	0.07		
Infection	3.44(1.08-12.77)	0.05*		
Hematoma	0.65(0.06-14.69)	0.73		

OR, odds ratio.

*Statistically significant (P < 0.05). Binomial regression of odds of postoperative complication v. none for adjunct type. Each model included the following covariates: age at index operation, smoking history, breast irradiation, plane of reconstruction (subpectoral versus prepectoral), and number of sheets of surgical adjunct used). Of note, odds ratios should be interpreted relative to *xenograft*.

Table 4. Comparison of Efficacy Outcomes between Xenograft and Allograft Groups, by Breast

Outcome	Xenograft	Allograft	Р
Primary efficacy endpoints			
Mean IFV \pm SD (mL)	341.5 ± 189.5	277.7 ± 148.3	< 0.01*
Mean IS± SD (mL)+	492.9 ± 140.0	567.9 ± 147.1	< 0.01*
Ratio, IFV:IS†	0.69 ± 0.33	0.46 ± 0.18	< 0.01*
Secondary efficacy			
endpoints			
Mean no. fills \pm SD	3.5 ± 2.9	5.2 ± 3.0	<0.01*
Mean TE-implant exchange	238.0 ± 133.6	245.7 ± 197.6	0.99
interval \pm SD (d)			

IFV, initial fill volume; IS, implant size; TE, tissue expander; d, days.

*Statistically significant (P < 0.05).

†Data unavailable for cases in which tissue expander was prematurely removed due to postoperative complication.

Table 5. Linear Regression of Efficacy Endpoints between Xenograft and Allograft Groups, by Breast

	I	FV	IF	V:IS	No.	Fills
Covariate	β	Р	β	Р	β	Р
Xenograft versus allograft	-5.3	0.83	-0.13	< 0.01*	1.2	0.01*
Age	0.59	0.54	0.003	0.11	-0.03	0.09
History of smoking	11.6	0.86	-0.01	0.93	0.64	0.60
Breast irradiation	-59.8	0.09	-0.08	0.26	0.56	0.43
Subpectoral versus pre- pectoral	111.1	<0.01*	0.16	<0.01*	-2.1	<0.01*
No. sheets used	39.5	0.14	0.11	0.03*	0.15	0.77

IFV, initial fill volume; IS, implant size.

*Statistically significant (P < 0.05). Linear regression of efficacy endpoints for adjunct type. Of note, covariates listed first in the columns were used as reference values during regression analysis, such that odds ratios should be interpreted relative to *xenograft* and *subpectoral* implant placement.

Artia has demonstrated a favorable complication profile when compared with commonly used allografts, no studies exist evaluating its efficacy in prosthesis-based breast reconstruction.^{14,15} This work utilizes previously validated endpoints for clinical efficacy of ADM, namely initial TE fill volume and ratio of initial TE fill volume to final implant size.⁴

Table 6. Patient and Operative Characteristics following Caliper-based Propensity Matching

Variable	Total (%)	Xenograft (%)	Allograft (%)	P
No. breasts	130	65 (50)	65 (50)	
Mean age±	52.0 ± 11.6	50.6 ± 12.5	53.5 ± 10.7	0.16
SD (Yr)				
No. obeset	41 (31.5)	18 (27.7)	23(35.4)	0.35
History of	61 (46.9)	32 (49.2)	29(44.6)	0.60
smoking Radiation Plane of	46 (70.8)	22 (33.8)	24 (36.9)	0.71
reconstruction Prepectoral Subpectoral No. sheets used \pm SD	$\begin{array}{c} 75 \; (57.7) \\ 55 \; (42.3) \\ 1.4 \pm \; 0.48 \end{array}$	$\begin{array}{c} 43 \ (66.2) \\ 22 \ (33.9) \\ 1.5 \pm 0.50 \end{array}$	$\begin{array}{c} 32 \ (49.2) \\ 33 \ (50.8) \\ 1.2 \pm 0.36 \end{array}$	<0.01*

*Statistically significant (P < 0.05).

+BMI>30.

Our analysis of unmatched patient cohorts revealed favorable xenograft safety and efficacy profiles when compared with allograft counterparts. Propensity matching was conducted to avoid confounding of differences in patient or surgical characteristics, such as age, radiation history, or plane of implant placement. Initial tissue expander fill volume is largely impacted by the viability of the mastectomy skin flap, where added tension to the skin envelope could predispose toward ischemia, implant exposure, or prosthesis failure. Because patients with robust mastectomy skin flaps are often selected for prepectoral implant placement and are, therefore, more likely to accommodate higher fill volume at the index operation, differences in operative plane between experimental groups would limit generalizability of results.⁴ In fact, our results confirm this phenomenon, where patients who underwent prepectoral breast reconstruction demonstrated greater initial fill volume (365.04 \pm 165.89 mL versus 217.42 \pm 127.29 mL, P < 0.01) and ratio of initial fill volume to final implant size $(0.67 \pm 0.27 \text{ versus } 0.41 \pm 0.22, P < 0.01)$ when compared with those who underwent subpectoral breast reconstruction, regardless of surgical adjunct used. Therefore, the variability in proportion of patients who underwent prepectoral breast reconstruction between allograft and xenograft groups was mitigated using propensity matching, after which no differences were observed in plane of reconstruction between matched cohorts. Rates of postoperative complication and efficacy metrics remained comparable between matched groups. As such, the results of our study suggest that Artia may be a safe and efficacious alternative to AlloDerm in alloplastic breast reconstruction when patient and surgical characteristics are controlled.

It has been proposed that ADM acts as a scaffold for autologous cell growth and revascularization, providing an additional layer of soft tissue support for the prosthesis.^{25,26} In vitro evaluation of fibroblast penetration suggests that human-derived ADM provides a network for development and remodeling of extracellular matrix, presumably conferring tensile strength and resistance to native breast tissue.^{27,28} Therefore, the efficacy of ADM as soft tissue reinforcement is likely due to its robust bio-integration, whereas synthetic materials, such as Vicryl mesh,

Outcome	Total	Xenograft (%)	Allograft (%)	Р
Tissue necrosis	28 (21.5)	17 (26.2)	11 (16.9)	0.20
Infection	18 (13.9)	5 (7.7)	13 (20.0)	0.04*
Hematoma	3 (2.3)	1 (1.6)	2(3.1)	0.99
Primary efficacy endpoints		× ,		
Mean $IFV \pm SD(mL)$	302.8 ± 166.2	317.3 ± 185.8	286.1 ± 140.4	0.51
Mean IS \pm SD (mL) \dagger	519.5 ± 152.2	493.6 ± 147.8	559.7 ± 152.1	0.05
Ratio, IFV:IS ⁺	0.59 ± 0.29	0.65 ± 0.33	0.48 ± 0.15	0.03*
Secondary Efficacy Endpoints				
Mean no. fills \pm SD	4.1 ± 2.9	3.7 ± 3.12	1.15 ± 0.4	0.04*
Mean TE-implant exchange interval \pm SD (d)	$239.7{\pm}143.5$	245.84 ± 129.6	232.3 ± 160.0	0.39

Table 7. Comparison of Safety and Efficacy Outcomes between Xenograft and Allograft Propensity-matched Groups via Univariate Analysis, by Breast

IFV, initial fill volume; IS, implant size; TE, tissue expander; d, days.

*Statistically significant (P < 0.05).

+Data unavailable for cases in which tissue expander was prematurely removed due to postoperative complication.

Table 8. Binomial Regression of Complication between Xenograft and Allograft Propensity-matched Groups, by Breast

	Allograft versus Xenograft			
Covariate	OR (95%CI)	Р		
Tissue necrosis	0.34 (0.11-1.07)	0.07		
Infection	3.18 (0.82–1.48)	0.11		
Hematoma	1.92 (0.08–175.23)	0.72		

OR, odds ratio.

*Statistically significant (P < 0.05). Binomial regression of odds of post-operative complication versus none for adjunct type. Each model included the following covariates: age at index operation, smoking history, breast irradiation, plane of reconstruction (subpectoral versus prepectoral), and number of sheets of surgical adjunct used). Of note, odds ratios should be interpreted relative to *xenografi*.

Table 9. Linear Regression of Efficacy Endpoints between Xenograft and Allograft Propensity-matched Groups, by Breast

	Ι	FV	IF	V:IS	No	Fills
Covariate	β	Р	β	Р	β	Р
Xenograft versus	25.9	0.31	-0.08	0.19	0.25	0.76
allograft						
Age	0.99	0.42	0.004	0.12	-0.03	0.19
History of smoking	-4.9	0.94	-0.02	0.86	1.0	0.48
Breast irradiation	-47.6	0.34	-0.12	0.28	-0.91	0.33
Subpectoral versus	119.7	< 0.01*	0.12	0.08	-2.0	< 0.01*
prepectoral No. sheets used	87	0.02*	0.21	< 0.01*	-0.64	0.35

IFV, initial fill volume; IS, implant size.

*Statistically significant (P < 0.05). Linear regression of efficacy endpoints for adjunct type. Of note, covariates listed first in the columns were used as reference values during regression analysis, such that odds ratios should be interpreted relative to *xenograft* and *subpectoral* implant placement.

are hydrolyzed over time. Artia has demonstrated comparable in vivo bio-integration to human-derived ADM within a murine model, with rapid angiogenesis and soft tissue ingrowth.²⁹ These results were repeated in a radiation fibrosis model, suggesting that Artia may even confer equivalent soft tissue support within irradiated wound beds. In addition, processing and terminal sterilization techniques for Artia reportedly minimize immunogenicity, thereby decreasing inflammatory responses that would otherwise adversely impact tissue healing and integration.¹⁴ Therefore, Artia appears to be biomechanically similar to AlloDerm, which could explain similarities in outcome observed in our study.

With the growing number of xenograft alternatives to human-derived ADM, investigation is necessary to validate clinical efficacy to facilitate widespread adoption of these surgical adjuncts for prosthesis-based breast reconstruction. The salient difference in cost between allograft and xenograft at the insurance and institution level has been well documented within the literature, with humanderived ADM demonstrating upwards of two-fold increase in cost-basis per unit.^{8,30} Despite the potential cost-effectiveness of xenograft surgical adjuncts, there remain significant barriers to its routine use in implant-based breast reconstruction.^{8,30-32} In fact, where the use of humanderived acellular dermal matrix for breast reconstruction remains an off-label indication, regulated by the Food and Drug Administration (FDA) as biologic tissue for use as soft tissue reinforcement of native breast tissue, nonhuman (porcine or other animal sources) ADM is instead described as a medical device, such that it requires clinical demonstration of safety and efficacy for its intended use.³⁰ Our demonstration of clinical efficacy of Artia, therefore, fills an important gap in knowledge, serving as a foundation upon which studies of xenograft efficacy can be performed.

The main limitation of this study is its retrospective nature. Efficacy metrics were defined as surrogate measures to evaluate soft tissue reinforcement, where a comprehensive assessment of ADM efficacy may involve other factors, including patient-reported outcomes. While outside the scope of this study, investigation is currently underway to compare patient-reported outcomes using the validated BREAST-Q questionnaire between xenograft and allograft groups. Furthermore, sub-group analysis based on plane of reconstruction demonstrated prepectoral breast reconstruction using Artia required a significantly greater number of sheets when compared to AlloDerm (n = 61, 1.80 ± 0.48 sheets versus n = 74, 1.33 ± 0.47 , respectively, P < 0.01). Admittedly, the size of allograft or xenograft sheet used was not documented within the medical record and, therefore, limits our ability to determine the total square centimeters of surgical adjunct per case, which would provide a better indication of utilization. To accommodate for this discrepancy, we constructed a linear regression model following propensity matching, which demonstrated that the initial fill volumes conferred by Artia and AlloDerm were comparable, even when holding the number of sheets constant. In other words, when using the same number of sheets of xenograft or allograft, initial tissue expander fill volumes were equivalent (Table 7). Whereas the price per unit of Artia is equivalent to that of AlloDerm, it stands to reason that, with greater adoption and improved scale of manufacture, cost-bases per unit or square centimeter are likely to decrease to approach those of other commonly used xenograft surgical adjuncts. As such, we may be able achieve a similar effect per unit of xenograft, at a decreased cost to the patient and institution. In addition, evaluation occurred at a tertiary academic center, which could introduce potential selection bias. Sample size was restricted by surgeon caseload, which may limit statistical power to draw conclusions given the low incidence of postoperative complications. Procedural details were not included, as recall bias and heterogenous methodologies present difficulties in retrospective analysis. Mastectomy type (nipple-sparing versus skin-sparing) was not recorded; however, previous studies have reported that postoperative complication rates and soft tissue reinforcement are comparable between the two methods.^{4,33,34} Despite these limitations, the results of this study are generalizable across surgeons who are experienced in prosthesis-based breast reconstruction and can therefore provide important insights for future work.

The strength of this study is its comparison of clinical efficacy endpoints between xenograft and allograft control groups within a large patient population. To the best of our knowledge, this work is the first to compare previously reported efficacy metrics between porcine-derived Artia and human-derived AlloDerm. A multi-institutional, randomized trial is necessary to prospectively evaluate soft tissue reinforcement conferred by xenograft surgical adjuncts. As innovation of acellular dermal matrices remains paramount to overcome limitations in supply and associated cost burden, these data can be utilized to help standardize the manufacture of graft materials for patients undergoing prosthesis-based breast reconstruction.

CONCLUSIONS

Our results suggest that porcine-derived Artia demonstrates comparable efficacy to human-derived AlloDerm in prosthesis-based breast reconstruction when patient and surgical demographics are well-matched. This is likely due to novel processing techniques and reliability in graft thickness and pliability, resulting in similar biomechanical properties between surgical adjuncts. This work serves as a foundation for future studies investigating the use xenograft surgical materials in alloplastic breast reconstruction.

> *Nikhil Sobti, MD* 593 Eddy Street, COOP 500 Providence, RI 02903 E-mail: niksobti@brown.edu

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