



# Incidence of Seromas and Infections Using Fenestrated versus Nonfenestrated Acellular Dermal Matrix in Breast Reconstructions

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**Background:** Acellular dermal matrices (ADMs) provide clinical benefits in breast reconstruction but have been associated with increased postoperative complications, most frequently seromas. Fenestration of the ADM before insertion into the reconstructed breast may reduce the incidence of postoperative complications. In this retrospective analysis, postoperative complications were assessed after breast reconstruction with or without fenestrated ADMs.

**Methods:** Patients who underwent immediate 2-staged implant breast reconstructions using ADM at a single center were assessed. The number of reconstructed breasts was stratified by ADM fenestration status and ADM type. The incidence of seroma, infection, extrusion, and explantation, and cosmetic score, was compared within the 2 stratified groups. A multivariable regression was performed to identify independent risk factors associated with these complications and aesthetic outcome.

**Results:** In total, data from 450 patients who had 603 breast reconstructions using either AlloDerm or FlexHD demonstrated a significantly higher incidence of seroma with nonfenestrated ADMs (20%) versus fenestrated ADMs (11%;  $P = 0.0098$ ). Rates of infection and explantation, and cosmetic score, were not influenced by fenestration status. In the multivariable analysis, ADM fenestration remained a significant protective factor for seroma formation. FlexHD also yielded a lower incidence of extrusion ( $P = 0.0031$ ) and a higher cosmetic score ( $P = 0.0466$ ) compared with AlloDerm after adjusting for other risk factors.

**Conclusions:** The results of this study support ADM fenestration for reduction of seroma incidence in breast reconstruction, without affecting cosmetic results. Additionally, the choice of ADM may reduce extrusion incidence and improve aesthetic outcomes. (*Plast Reconstr Surg Glob Open* 2015;3:e569; doi: 10.1097/GOX.0000000000000559; Published online 20 November 2015.)

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Acellular dermal matrices (ADMs) provide structural strength, promote vascularization, and can serve as a scaffold for formation of new tissue. In addition, clinical evidence indicates that the incidence of capsule contracture may be reduced.<sup>1,2</sup> These properties have made the use of ADMs increasingly common in immediate breast re-

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constructions with expanders and implants.<sup>3</sup> However, there is controversy regarding the effect of ADMs on the incidence of postoperative complications. The ADM is designed to function as a graft, and anything that interferes with early revascularization and tissue ingrowth can prevent “take” of the ADM, or graft. Flap ischemia, bacterial seeding, and seroma can all lead to explantation, with seroma being the most common complication reported in breast reconstructions using ADMs.<sup>4</sup> Drains are used to prevent fluid collection between the ADM and skin tissue, and in one recent survey, 95% of surgeons placed a drain in conjunction with ADM during breast reconstruction.<sup>3</sup> Furthermore, 57.5% of those surgeons using drains reported that they left them in for longer time periods when they used ADMs versus without, which may contribute to an increased risk of infection.<sup>3,4</sup> Although having a drain in place may reduce the risk of seroma when using ADMs in breast reconstruction, the clinical evidence is inconsistent and reports a wide range (3–31%) of patients who experience a seroma after drain removal.<sup>4,5</sup>

Management of seroma is typically aspiration, catheter placement, and/or irrigation and drain placement, depending on the volume of fluid collection.<sup>4</sup> In addition, seromas may require multiple drainage procedures. One of the key factors identified for successful completion of reconstruction was early ingrowth of the patient’s tissue into the ADM, and theoretically, seromas interfere with this process, leading to infection, extrusion, and reconstruction failure.

A technique that could potentially increase allograft effacement with the skin tissue and reduce seroma incidence may be fenestration of the ADM before insertion into the reconstructed breast. Subsequently, a reduction in seroma could decrease the incidence of infection and implant loss. However, the clinical evidence on these topics is scarce. A retrospective chart review in 42 patients with 70 two-stage breast reconstructions reported integration of fenestrated ADM at the time of implant exchange (mean time to full expansion, 89.5 days), and improved intraoperative fill volume and subjective cosmetic outcome, increased expansion rate with subjectively less pain, and decreased number of postoperative expansions with ADM fenestration versus without fenestration.<sup>6</sup> Different types of ADM were used in these reconstructions, but no formal statistics were performed to assess the influence on outcomes. In addition, in 1 surgical group in this small patient cohort (N = 30), only rare occurrences of seroma formation were observed with use of fenestrated ADMs in breast reconstruction.<sup>7</sup>

With the goal of understanding the effects of fenestrated ADM on postoperative complications, a retrospective analysis of a relatively large series of expander and implant immediate breast reconstructions with or without fenestrated ADMs was conducted to evaluate the incidence of seroma and infections, as well as explantation and cosmetic score. Also evaluated were the reconstructive results by ADM type: AlloDerm (Lifecell and Acelity Corporation, Branchburg, N.J.) or FlexHD (Musculoskeletal Transplant Foundation, Edison, N.J.). As the center used AlloDerm and FlexHD interchangeably, this allowed us to perform a multivariable statistical analysis to examine the effects of both fenestration and ADM type on postoperative outcomes.

## METHODS

### Study Design and Patients

Eligible patients had immediate 2-staged implant breast reconstructions performed at the Northern Westchester Surgical Services group by surgeons with similar techniques (2 oncologic breast surgeons and 3 reconstructive plastic surgeons) from 2006 to 2011. Patients were excluded if an ADM was not used in the reconstruction surgery. All patients provided written consent, and patient information was de-identified, complying with the Health Insurance Portability and Accountability Act. The study was approved by the hospital’s Institutional Review Board.

### Data Collection

Patient demographic and baseline characteristic data were collected for age, body mass index, and preoperative status for diabetes mellitus, smoking, and radiation exposure. Operative details were also collected for reconstructed breast number, ADM type, whether ADM fenestration was performed, and expander size and fill volume. Postoperative data were collected for at least 6 months after the last-stage reconstruction or last-reported complication. Specifically, data were collected for seroma, infection, extrusion, explantation, and cosmetic score. Extrusion was defined as a complication resulting in lack of adequate tissue coverage, leading to exposure of the expander, or implant through the skin. Explantation was defined as a complication resulting in the removal of the expander or implant and subsequent reconstruction failure. Cosmetic score was blindly evaluated for aesthetics on a scale of 1 to 10 (higher score indicates better aesthetic result) by 2 surgeons and 1 layperson for each patient. An overall cosmetic score for each patient was calculated by averaging the 3 raters’ assigned scores.

**Fenestration Technique**

For patients who had their ADM fenestrated, AlloDerm, which requires rehydration, was soaked in saline for at least 45 minutes before fenestration; and FlexHD, which comes prehydrated, was available for immediate fenestration. For both allograft types, a series of fenestrations through the full thickness of the allograft was made with an 11 or 15 scalpel set at intervals of approximately 1 cm. In all cases for each type of ADM, a 6 × 16 cm graft was used (96 cm<sup>2</sup>), minimizing graft surface area as a variable. The decision to fenestrate an ADM was according to the surgeon’s discretion; there was no preset determination. All surgeons fenestrated a similar number of ADMs over the 5-year time frame of the study.

**Statistical Analysis**

Descriptive statistics were generated for all demographic and surgical procedure-related and postoperative outcome variables. Student *t* tests for continuous variables and  $\chi^2$  tests for categorical variables were conducted to compare patient characteristics and postoperative outcomes, including seroma, infection, extrusion, explantation, and cosmetic score, between fenestrated and nonfenestrated patients, as well as between AlloDerm and FlexHD groups. For postoperative outcomes other than cosmetic score, the number of breast reconstructions was used for analysis. Multivariable mixed-effects logistic regression models, adjusting for nesting effect of multiple breast reconstructions within the same patient, were performed for binary complication outcomes (seroma, infection, extrusion, and explantation). A multiple linear regression model was conducted for numeric aesthetic outcome (cosmetic score). A 2-tailed *P* value of less than 0.05 was considered significant. All statistical

analyses were performed using SAS 9.4 statistical software (SAS Inc., Cary, N.C.).

**RESULTS**

**Patients**

A total of 450 patients who had 603 breast reconstructions using either AlloDerm or FlexHD were included in this analysis. Among the 603 immediate reconstructions, 488 (81%) received fenestrated ADM and 115 (19%) received nonfenestrated ADM. The rate of fenestrated and nonfenestrated ADM use was consistent throughout the 5-year study period. Patient demographics were similar between the FlexHD and AlloDerm groups with the exception of mean expander fill size, which was greater in the FlexHD group (Table 1). Patient demographics were also similar between fenestrated and nonfenestrated ADM groups with the exception of radiation treatment, which was higher in the fenestrated group. Drains were removed between 4 and 21 days postoperatively, with a mean of 6.7 days, based on the drains having achieved a state of removing 30 mL or less over the prior 24-hour period.

**Postoperative Outcomes**

**Seroma Incidence**

A total of 77 (13%) cases of seroma were reported among the 603 breast reconstructions analyzed and in similar proportions of patients with each type of ADM [FlexHD, 52 of 424 (12%) reconstructions; AlloDerm, 25 of 179 (14%) reconstructions; *P* = 0.5672]. However, a significantly higher proportion of patients experienced a seroma with nonfenestrated ADM breast reconstruction (20%) compared with fenestrated ADM breast reconstruction (11%; *P* = 0.0098; Table 2). These results were similar for both ADM types.

**Table 1. Patient Demographics and Baseline Characteristics**

	AlloDerm (n = 134)	FlexHD (n = 316)	<i>P</i>	Fenestrated (n = 362)	Nonfenestrated (n = 88)	<i>P</i>
Mean age, yr (SD) (range, 31–80)	53.4 (9.5)	52.6 (8.3)	0.4107	52.9 (8.8)	53.0 (8.2)	0.9262
Mean BMI, kg/m <sup>2</sup> (SD) (range, 17.3–44.6)	26.7 (4.5)	26.5 (3.6)	0.7237	26.6 (3.9)	26.3 (3.9)	0.5330
Radiation, n (%)	15 (11.2)	41 (13.0)	0.6008	51 (14.1)	5 (5.7)	0.0310
Smoking, n (%)	17 (12.7)	43 (13.6)	0.7927	53 (14.6)	7 (8.0)	0.0979
Diabetes, n (%)	5 (3.7)	9 (2.9)	0.5691	9 (2.5)	5 (5.7)	0.1215
Type of construction, n (%)						
One breast	89 (66.4)	208 (65.8)	0.9030	236 (65.2)	61 (69.3)	0.4638
Both breasts	45 (23.6)	108 (34.2)		126 (34.8)	27 (30.7)	
Fenestration, n (%)						
Yes	103 (76.9)	259 (82.0)	0.2126	103 (28.5)	31 (35.2)	0.2126
No	31 (23.1)	57 (18.0)		259 (71.5)	57 (64.8)	
Mean expander size, cm (SD) (range, 150–800)	513 (104)	540 (107)	0.0134	533 (107)	528 (105)	0.6556
Mean expander fill, mL (SD) (range, 50–600)	164 (63)	162 (69)	0.7684	164 (70)	154 (60)	0.2385

BMI, body mass index; SD, standard deviation.

**Table 2. Postoperative Complications by Fenestration Status and ADM Type**

Complication	AlloDerm (BRs = 179), N (%)	FlexHD (BRs = 424), N (%)	P	Fenestrated (BRs = 488), N (%)	Nonfenestrated (BRs = 115), N (%)	P
Seroma	25 (14.0)	52 (12.3)	0.5672	54 (11.1)	23 (20.0)	0.0098
Infection	20 (11.2)	39 (9.2)	0.4558	46 (9.4)	13 (11.3)	0.5420
Extrusion	11 (6.2)	8 (1.9)	0.0062	16 (3.3)	3 (2.6)	0.9999
Explantation	16 (8.9)	31 (7.3)	0.4959	37 (7.6)	10 (8.7)	0.6886

ADM, acellular dermal matrix; BRs, breast reconstructions.

**Infection Incidence**

Fifty-nine (10%) cases of infection were reported among all of the breast reconstructions analyzed, with no statistically significant difference by fenestration status and ADM type. Among the patients who received FlexHD, 39 of 424 (9%) reconstructions resulted in an infection, and among the patients who received AlloDerm, 20 of 179 (11%) reconstructions resulted in an infection ( $P = 0.4558$ ). Similarly, among the patients who had fenestrated ADM breast reconstruction, 9% of the reconstructions resulted in an infection, and for patients who had nonfenestrated ADM breast reconstruction, 11% of reconstructions resulted in an infection ( $P = 0.5420$ ; Table 2). These results were similar in both ADM types.

**Extrusion**

Nineteen (3%) cases of extrusion were reported among all of the breast reconstructions analyzed, with no statistically significant difference by fenestration status. However, the AlloDerm group had a significantly higher incidence rate of extrusion (6.2%) compared with the FlexHD group (1.9%;  $P = 0.0062$ ; Table 2). These results were similar by fenestration status.

**Explantations**

Forty-seven (8%) explantations were reported among all of the breast reconstructions analyzed, with no statistically significant difference by fenestra-

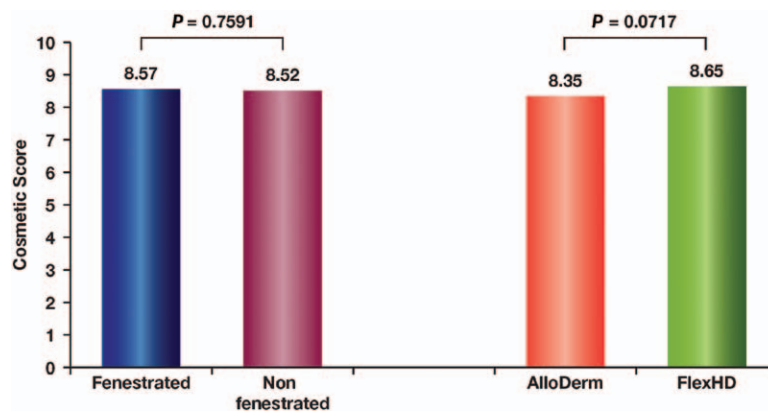
tion status and ADM type. Among the patients who received FlexHD, 31 of 424 (7%) reconstructions resulted in an explantation, and for patients who received AlloDerm, 16 of 179 (9%) reconstructions resulted in an explantation ( $P = 0.4959$ ). Similarly, among the patients who had fenestrated ADM breast reconstruction, 8% of the reconstructions resulted in an explantation, and for patients who had nonfenestrated ADM breast reconstruction, 9% of reconstructions resulted in an explantation ( $P = 0.6886$ ; Table 2). These results were similar in both ADM types.

**Cosmetic Score**

The cosmetic score between ADM types and fenestration groups is illustrated in Figure 1. Overall, the mean cosmetic score was  $8.6 \pm 1.6$ , and was similar between fenestrated ( $8.6 \pm 1.6$ ) and nonfenestrated groups ( $8.5 \pm 1.6$ ;  $P = 0.7591$ ). However, the FlexHD group trended toward a higher mean cosmetic score ( $8.7 \pm 1.5$ ) compared with the AlloDerm group ( $8.4 \pm 1.7$ ;  $P = 0.0717$ ).

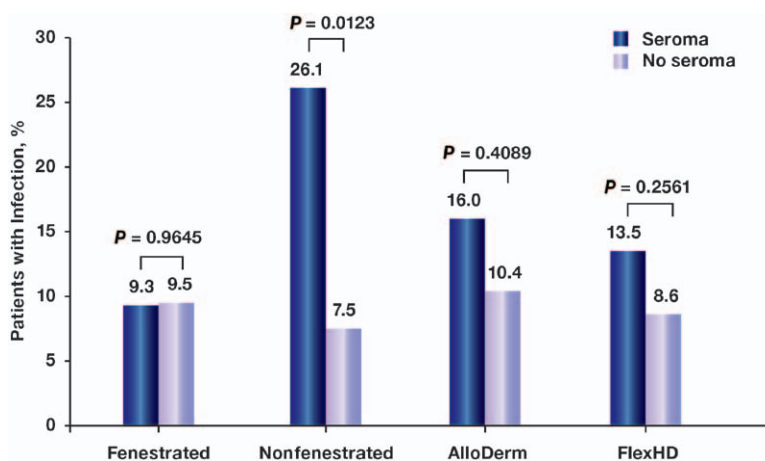
**Association between Seroma and Infection**

We further examined the association between seroma and infection by ADM type and fenestration groups; the results are illustrated in Figure 2. Among patients who had nonfenestrated ADM breast reconstruction, there was a significantly higher risk



**Fig. 1.** Mean cosmetic score by fenestration status and acellular dermal matrix (ADM) type.





**Fig. 2.** Infection incidence by fenestration status and acellular dermal matrix (ADM) type.

of infection in patients who had a seroma than in those who did not (26% versus 8%, respectively;  $P = 0.0123$ ). Among patients who had fenestrated ADM breast reconstruction, there was no significant difference in infection incidence between the seroma and no-seroma groups (9% versus 10%, respectively;  $P = 0.9645$ ). There was also no significant difference in infection incidence between the seroma and no-seroma groups in patients who received FlexHD (14% versus 9%, respectively;  $P = 0.2561$ ) and patients who received AlloDerm (16% versus 10%, respectively;  $P = 0.4089$ ).

#### Multivariable Model for Postoperative Outcomes

Among all of the variables examined in the risk-adjusted multivariable model, fenestration remained a significant protective factor for postoperative seroma (odds ratio = 0.34;  $P = 0.0026$ ; Table 3). However, fenestration was not an independent predictor of postoperative infection ( $P = 0.1399$ ), extrusion ( $P = 0.8999$ ), explantation ( $P = 0.2841$ ), or cosmetic score ( $P = 0.2858$ ). Of note, patients who received FlexHD exhibited significantly lower postoperative extrusion ( $P = 0.0031$ ) and higher postoperative cosmetic score ( $P = 0.0466$ ) than patients who received AlloDerm, after adjusting for other risk factors. Other significant predictors for increased postoperative complications and inferior cosmetic score included radiation treatment for all assessed outcomes, smoking and higher expander fill volume for infections and cosmetic score, and greater body mass index for extrusion and cosmetic score (Table 3).

## DISCUSSION

Clinical evidence suggests that the use of ADMs in breast reconstruction increases the incidence of seromas compared with no ADM use, as confirmed

by a number of previously published studies.<sup>8–10</sup> However, the evidence is inconsistent. Nevertheless, seromas can increase the risk of infections and lead to implant loss, especially as the severity of fluid retention increases.<sup>4</sup> With the goal of further reducing the incidence of seromas, 1 option is the fenestration of the ADM before insertion, although few publications report clinical evidence on this procedure and whether it influences the incidence of seroma and/or infections.<sup>2,6</sup>

The rationale behind fenestration of ADM and the reduction of seroma incidence is the hypothesis that fenestration improves the effacement of the ADM and the skin flaps. The increase in surface area between ADM and skin tissue may allow faster vascular ingrowth, which, in turn, could reduce the time available for fluid collection. In addition, the fenestrations may allow more rapid efflux of fluid into the drains, with less accumulation of fluid between the ADM and the breast flaps and thus fewer seromas.

This relatively large retrospective analysis of 450 patients with 603 breast reconstructions undertook the evaluation of seroma incidence among fenestrated and nonfenestrated ADMs and showed that the seroma incidence among fenestrated ADMs was significantly lower than that of nonfenestrated ADMs. These results were similar regardless of the type of ADM used. In addition, infection rate was highest among patients with nonfenestrated ADM who developed a seroma, suggesting that this subset of patients was at greater risk of developing an infection. In general, the 10% infection rate reported in this study is within the range of infection rates reported by other recent studies using ADMs in breast reconstructions (2–20%),<sup>11–17</sup> although fenestration status in those recent ADM studies was not specified. Similarly, the 8% explantation rate reported in this study

**Table 3. Multivariable Regression Analysis\* for Postoperative Outcomes**

Variables	Seroma		Infection		Extrusion		Explantation		Cosmetic Score	
	OR	P	OR	P	OR	P	OR	P	b	P
Fenestration (yes vs no)	0.34	0.0026	0.52	0.1399	0.93	0.8999	0.58	0.2841	0.245	0.2858
ADM type (AlloDerm vs FlexHD)	0.84	0.7408	1.19	0.7877	4.30	0.0031	1.25	0.7547	-0.361	0.0466
ADM type × Fenestration†	1.57	0.4545	1.34	0.6845	0.24	0.3668	1.23	0.7983	-0.395	0.6603
Age	1.02	0.2380	1.01	0.6080	1.00	0.9396	1.01	0.5686	0.005	0.5808
BMI	1.02	0.6379	1.04	0.2807	1.17	0.0047	1.07	0.1169	-0.045	0.0385
Radiation (yes vs no)	3.71	<0.0001	3.61	0.0006	6.02	0.0014	3.22	0.0048	-0.765	0.0007
Smoking (yes vs no)	1.27	0.5204	2.74	0.0052	1.35	0.6504	2.20	0.0518	-0.438	0.0444
Diabetes (yes vs no)	1.43	0.5879	0.61	0.6357	0.95	0.9710	0.75	0.7838	-0.022	0.9596
Expander size	1.00	0.5550	1.00	0.1194	1.00	0.6760	1.00	0.1518	-0.001	0.2070
Expander fill volume	1.00	0.0869	1.01	0.0222	1.00	0.2146	1.00	0.0645	-0.004	0.0052

\*Multiple breast constructions within the same patient were modeled as nested effect.

†ADM type and fenestration interaction.

ADM, acellular dermal matrix; b, coefficient estimate; BMI, body mass index; OR, odds ratio.

was within the range reported among those recent ADM studies (4–11%).<sup>12,14,15,17</sup>

Our data showed no statistical difference in seroma or infection rate with FlexHD compared with AlloDerm. This finding held true in a larger series of postmastectomy breast reconstructions that Rosenberg et al examined using the same cohort.<sup>10</sup> However, the authors found that there was a slightly higher numeric incidence of seroma and infection with AlloDerm (15.1% and 11.2%, respectively) compared with FlexHD (11.9% and 9.1%, respectively).

In other published literature, there is general agreement that the complication rate between AlloDerm and FlexHD is similar. In a retrospective, smaller subset analysis (262 breast reconstructions) using an ADM, FlexHD and AlloDerm were similar with regard to rates of infection, seroma, and explantation in implant-based immediate reconstructions.<sup>18</sup> However, in the multivariable analysis of this subset, FlexHD was associated with higher implant loss compared with AlloDerm ( $P = 0.042$ ). Because implant loss was not clearly defined in this publication, the rationale for this association remains unclear. In another smaller, retrospective, multivariable analysis of factors for seroma (284 breast reconstructions, 220 of which used ADM), the authors found no difference in the total complication or infection rate between AlloDerm and FlexHD ( $P \geq 0.47$  for both).<sup>8</sup> Interestingly, FlexHD had a lower incidence of extrusion and scored higher than AlloDerm on our cosmetic scale, a finding that was statistically significant in our multivariable analysis.

This study, like the earlier studies, holds all the inherent challenges associated with reliance on retrospective studies to guide the clinician. In addition, because breast reconstructions in this study were performed before the availability of commercially prepared fenestrated ADM, manual fenestration was performed. Although this may induce some varia-

tion in the final product used in the reconstructions, variations in surface area are likely to be negligible because the same-size ADMs were used. Our sample size, which included 603 breast reconstructions, was larger than those in the previous publications. This study supports the hypothesis that fenestration of the ADM can reduce the incidence of seromas in breast reconstruction, without affecting the cosmetic results, and that choice of ADM may reduce the incidence of extrusions and improve aesthetic outcomes. Prospective studies to further elucidate the potential benefits associated with fenestration of the ADM are needed to guide the reconstructive plastic surgeon.

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