The advent of acellular dermal matrix has significantly improved techniques for implant-based breast reconstruction. Acellular dermal matrices are decellularized soft-tissue grafts that provide soft-tissue reinforcement and a foundation on which vascularization and autologous cell growth can occur. These properties of acellular dermal matrix can improve the positioning of the prosthesis and provide a more natural aesthetic outcome. Various investigations have been conducted to determine the advantages of matrix-based reconstruction. Acellular dermal matrix has been associated with higher initial fill volume, resistance to irradiation effects such as capsular contracture, and increased rate of direct-to-implant breast reconstruction. As with any new procedure, use of acellular dermal matrix has been associated with a higher risk of developing surgical-site infection. The infection rate was not statistically different between patients who received FlexHD versus AlloDerm on either univariate or binomial regression analysis. Likewise, there were no statistical differences in rates of seroma, hematoma, explantation, or delayed wound healing.

**Background:** The use of acellular dermal matrix has facilitated immediate prosthesis-based breast reconstruction. However, few studies directly compare surgical outcomes following acellular dermal matrix–based reconstruction with two of the most commonly available materials, AlloDerm and FlexHD. Those studies that are available often do not adequately control for the surgeon as a variable. The authors hypothesize that complication rates will not differ significantly between AlloDerm and FlexHD when practice and surgeon variables are properly controlled.

**Methods:** Retrospective review was conducted to identify consecutive implant-based reconstruction procedures performed at a tertiary academic medical institution by a single plastic surgeon over 6 years. Univariate and binomial regression analyses were conducted to compare patient characteristics and clinical endpoints across acellular dermal matrix groups (AlloDerm/AlloDerm ready-to-use versus FlexHD Pliable/Perforated).

**Results:** Of the 233 patients that underwent matrix-based breast reconstruction, 11 (4.7 percent) developed surgical-site infection. The infection rate was not statistically different between patients who received FlexHD [n = 5 (5.0 percent)] versus AlloDerm [n = 6 (4.6 percent)] on either univariate (p = 0.89) or binomial regression analysis (p = 0.56). Likewise, there were no statistical differences in rates of seroma, hematoma, explantation, or delayed wound healing.

**Conclusions:** Clinical endpoints of interest were all equivalent between acellular dermal matrix types. This study uniquely reports a single-surgeon case series comparing outcomes between different acellular dermal matrix types. Instead of focusing on acellular dermal matrix as a predictor of outcome, other patient and surgeon factors should be addressed to improve results and innovate better alternatives. (Plast. Reconstr. Surg. 138: 959, 2016.)

**Clinical Question/Level of Evidence:** Therapeutic, III.
postoperative complications early in the surgeon’s learning curve.\textsuperscript{16–17} However, as surgeons have gained experience in acellular dermal matrix–mediated breast reconstruction, complication rates have decreased and stabilized.\textsuperscript{15,18–20}

Within the past decade, over half of all tissue-expander or implant-based reconstructions (56 percent) performed in the United States have incorporated acellular dermal matrix.\textsuperscript{21} Widespread acceptance among both patients and plastic surgeons has encouraged the manufacture of various acellular dermal matrix products. Currently, two of the most commonly used acellular dermal matrix types are FlexHD (Musculoskeletal Transplant Foundation, Edison, N.J.) and AlloDerm (LifeCell Corp., Branchburg, N.J.). As depicted in Figure 1, the preparation of the two acellular dermal matrix types requires procurement of cadaveric tissue, removal of the epidermis, decellularization, sterilization, and processing. Fundamental differences exist in the chemical agents used to “de-epidermize” and sterilize the donor tissue. (The term “de-epidermize” was used in U.S. patent 5,336,616 to describe the processing of cadaveric tissue in preparation for use as acellular dermal matrix.) Furthermore, the handling techniques in the final stages of preparation contrast vastly between manufacturers, as AlloDerm is freeze-dried before packaging, whereas FlexHD remains hydrated.\textsuperscript{22,23} In recent years, a hydrated version of AlloDerm has been introduced, AlloDerm ready-to-use, which does not require the 30-minute interval of rehydration characteristic of its predecessor.\textsuperscript{24}

The variation among acellular dermal matrix types has raised questions regarding the comparative advantages and disadvantages of the products. Few studies have been conducted that directly compare the outcomes following use of AlloDerm and FlexHD. Determining differences in complication rates is necessary to ensure that the appropriate material is being used and holds implications in maintaining patient satisfaction, minimizing costs, and improving quality of life. Given the apparent product bias and lack of control for surgeon

![Fig. 1. Direct comparison of preparation and harvest of acellular dermal matrices (ADM), FlexHD and AlloDerm (RTU), based on U.S. patents 7,723,108 and 5,336,616, respectively, and description by Yuen et al. Note that the processing techniques between the two acellular dermal matrix types are very similar. Although there are differences in the buffers, washing solutions, and certain treatments, the acellular dermal matrix preparation steps are comparable.](https://www.plast Reconstr Surg.2016.11.0000)
factors in the available literature, AlloDerm and FlexHD have yet to be accurately compared. This study tests the hypothesis that despite the variance in construct of AlloDerm and FlexHD, no significant differences exist in postoperative complication rates when practice and surgeon variables are properly controlled.

**PATIENTS AND METHODS**

**Study Design and Patient Population**

Approval by the institutional review board was obtained with a waiver of informed consent. A retrospective chart review was performed to identify consecutive patients who underwent acellular dermal matrix–based reconstruction using either AlloDerm or FlexHD performed by a single plastic surgeon between September of 2009 and October of 2015 at a tertiary academic medical center. Only acellular dermal matrix use in the index case following mastectomy was recorded. The type of AlloDerm used was either ready-to-use (RTU) or freeze-dried, whereas the FlexHD primarily used was Pliable Perforated. These were the most commonly used acellular dermal matrix preparations in the United States over the study period. Our institution had these acellular dermal matrix types on consignment and the surgeon was free to use whichever acellular dermal matrix for any given case. The acellular dermal matrix preparations were used interchangeably based on availability, resulting in patients with reconstructions of varying acellular dermal matrix types.

**Data Collection**

Chart review was performed to obtain patient characteristics, comorbidities, treatment history, and surgical outcomes. Variables collected for each patient were type of acellular dermal matrix used, age at surgery, body mass index, implant size, smoking status, history of breast irradiation, neoadjuvant chemotherapy, average specimen size, and laterality (bilateral versus unilateral). The follow- ing postoperative complications were identified: seroma, hematoma, implant removal (explant), delayed wound healing (tissue necrosis), and surgical-site infection. The clinical endpoint of infection was defined using criteria established by the Centers for Disease Control and Prevention for deep incisional surgical-site infection and organ/ space surgical-site infection as follows: (1) incidence of purulent drainage; (2) presence of positive culture from any operative exploration; or (3) evidence of infection on examination requiring hospital admission and/or surgical exploration within 90 days of an operative procedure. As implant removal could have occurred because of factors unrelated to acellular dermal matrix, such as self-injury (one patient suffered thermal injury from a hot water bottle), residual malignancy, and patient dissatisfaction, explantation was recorded only with respect to infection or skin flap viability. It is this surgeon’s practice to not keep any drain longer than 2 weeks postoperatively; all seromas were managed with needle aspiration by the surgeon in the office and did not require any additional imaging or intervention. For patients who exhibited concurrent clinical endpoints of interest, the postoperative complication that occurred first was identified and recorded. Body mass index was calculated as mass/meters squared.

A literature search was conducted using MEDLINE to identify retrospective cohort studies that directly compared postoperative complication rates between AlloDerm and FlexHD from 2010 to 2015. For inclusion, articles had to report surgical outcomes following immediate acellular dermal matrix–based breast reconstruction. The following data were extracted: total number of FlexHD procedures, total number of AlloDerm procedures, and infection rates for the two acellular dermal matrix types, respectively.

**Statistical Analysis**

Statistical analysis was conducted with IBM SPSS Version 23 (IBM Corp., Armonk, N.Y.). Power analysis was conducted to determine the sample size necessary to detect an effect size of 7.4 percent, by breast, which represents the largest recorded variance in infection rate between AlloDerm and FlexHD. A \( z \) test for difference between two independent proportions was conducted at a significance of 0.05 and power of 80 percent. We calculated an a priori sample size of 376 breasts. The final sample consisted of 224 and 170 breasts within the AlloDerm and FlexHD groups, respectively. Adjustments were made to accommodate an allocation ratio of 1.32 (N2/N1), which yielded a statistical power of 82.2 percent.

Patient characteristics between the two acellular dermal matrix groups were compared by univariate analysis. Chi-square testing was used for categorical variables such as history of smoking, oncologic management, surgical indication, and postoperative complications. A Shapiro-Wilk test was conducted to test for normality among continuous variables. Age at surgical intervention was
analyzed using the t test for normally distributed variables. Nonnormal characteristics such as body mass index, implant size, and specimen size were compared using the Mann-Whitney test. Outcome data were analyzed by unadjusted logistic regression both by patient and by breast, assuming that outcomes for each breast were independent events. Breast-specific data were included to allow for better comparison to similar studies in the available literature. A binomial regression model was constructed to investigate the association between covariates (i.e., acellular dermal matrix type, age at surgical intervention, body mass index, smoking status, implant size, neoadjuvant chemotherapy, and history of radiation therapy) and complications. For each patient characteristic controlled for by the model, an odds ratio, 95 percent confidence interval, and p value were calculated. Statistical significance was defined as p < 0.05.

RESULTS

Population Characteristics

Our database identified 233 patients who underwent either bilateral (n = 161) or unilateral (n = 72) mastectomy followed by immediate reconstruction, resulting in a total of 394 ADM-based breast reconstruction procedures. A total of 218 (93.6 percent) patients underwent direct-to-implant breast reconstruction, whereas 15 received tissue expander placement. The most common indication for mastectomy was diagnosis of breast cancer, whereas 22 patients elected to undergo prophylactic mastectomy because of genetic predisposition from deleterious BRCA1/2 or CDH1 mutations. The mean age of the women was 49.6 ± 10.0 years. Table 1 presents clinical characteristics of the total cohort and by acellular dermal matrix type. All groups are comparable without statistically significant variation between body mass index, smoking status, and radiation treatment.

Outcomes

AlloDerm was used in 224 breasts (132 patients), whereas FlexHD was used in 170 breasts (101 patients). A mix of ready-to-use (68.9 percent) and freeze-dried AlloDerm (31.1 percent) was used during the interval of observation. Although FlexHD Pliable/Perforated was used in the majority of FlexHD cases (80.2 percent), patients also received both FlexHD Pliable (18.8 percent) and FlexHD Structural (0.9 percent). The most common postoperative complication across both groups was seroma, which occurred in 15.9 percent of the patients, followed by explantation (6.4 percent). A total of 11 patients (4.7 percent) developed surgical-site infection, nine patients developed hematoma, and 13 experienced delayed wound healing that required correction (Tables 2 and 3). Of the patients who developed surgical-site infection, a total of five (45 percent) had a history of either preoperative (n = 2) or postoperative (n = 3) radiation therapy. Although the rate of radiation is higher in the infection group than in the noninfection group, this variation was not statistically significant (Table 4).

Table 1. Patient Characteristics for Total Cohort and by Acellular Dermal Matrix Type*

| Variable                        | Total (%) | AlloDerm (%) | FlexHD (%) | p     |
|---------------------------------|-----------|--------------|------------|-------|
| No. of patients                 | 233       | 132          | 101        |       |
| No. of breasts                  | 394       | 224          | 170        |       |
| No. of unilateral procedures    | 72 (30.9) | 40 (30.3)    | 32 (31.7)  |       |
| No. of bilateral procedures    | 161 (69.1)| 92 (69.7)    | 69 (68.3)  |       |
| No. of DTI reconstructions      | 218 (93.6)| 119 (90.2)   | 99 (98.0)  |       |
| No. of TE placements           | 15 (6.4)  | 13 (9.9)     | 2 (2.0)    |       |
| Mean age ± SD, yr              | 49.6 ± 10.0| 49.7 ± 10.0 | 49.4 ± 10.2| 0.80  |
| Mean BMI ± SD, kg/m²†          | 25.8 ± 5.3| 25.9 ± 5.5   | 25.6 ± 5.2 | 0.67  |
| Mean implant size ± SD, × 100 ml| 4.4 ± 1.4 | 4.5 ± 1.4   | 4.3 ± 1.5  | 0.37  |
| Mean specimen size ± SD, × 100 g| 5.4 ± 3.2 | 5.7 ± 3.5   | 5.0 ± 2.7  | 0.23  |
| Prophylactic mastectomy        | 22 (9.4)  | 10 (7.6)     | 12 (11.9)  | 0.27  |
| Cosmetic procedure             | 2 (0.86)  | 2 (1.5)      | 0 (0)      | 0.21  |
| History of smoking             | 68 (29.2) | 42 (31.8)    | 26 (25.7)  | 0.31  |
| Chemotherapy                    | 95 (40.8) | 57 (43.2)    | 38 (37.6)  | 0.39  |
| Radiation                       | 71 (30.5) | 43 (32.6)    | 28 (27.7)  | 0.43  |
| Preoperative                    | 17 (7.3)  | 11 (8.3)     | 6 (5.9)    |       |
| Postoperative                   | 54 (23.2) | 32 (24.2)    | 22 (21.8)  |       |

DTI, direct-to-implant; TE, tissue expander; BMI, body mass index.

*χ² test was performed for categorical values; t test was performed for continuous values.
†Data unavailable for two patients.
‡Data unavailable for 49 patients.
Acellular Dermal Matrices (AlloDerm versus FlexHD)

As indicated in the univariate analysis, there were no significant differences in complication rates between the acellular dermal matrix groups. There was a comparable rate of infection in the patients who received FlexHD \( (n = 5) \) compared with those who received AlloDerm \( (n = 6) \) (5.0 percent versus 4.6 percent; \( p = 0.89 \)). By accounting for potential confounding factors in a binomial regression analysis, we found that the difference in infection rates among acellular dermal matrix groups was not statistically significant (OR, 0.69; 95 percent CI, 0.17 to 2.56; \( p = 0.56 \)). A similar result is observed when comparing the two groups by breast (OR, 0.78; 95 percent CI, 0.22 to 2.72; \( p = 0.69 \)). Therefore, neither FlexHD nor AlloDerm was an independent predictor of infection. There were no other significant differences in postoperative outcomes between AlloDerm and FlexHD (Table 5).

Meta-Analysis of the Current Literature

Five peer-reviewed studies exist that directly compare outcomes following implant-based reconstruction with either FlexHD or AlloDerm (Table 6).\textsuperscript{25–29} A systematic review of the literature was performed to obtain complication rates. The primary outcome of interest was surgical-site infection, which was commonly defined using Centers for Disease Control and Prevention criteria. A weighted average of infection rates was calculated for the two acellular dermal matrix types, by breast. FlexHD exhibited a 10 percent rate of infection compared to 9.0 percent for AlloDerm (\( p = 0.45 \)). Only one of the five studies reported a statistical significance in infection rate between the two acellular dermal matrix types.\textsuperscript{25}

DISCUSSION

Acellular dermal matrices have become increasingly common in implant-based reconstructive procedures. Some of the reported advantages include improved lower pole contour, facilitated implant positioning, reduced interval of tissue expansion, and increased options for direct-to-implant single-stage immediate reconstruction.\textsuperscript{30–32} Although acellular dermal matrices have simplified surgical technique and improved aesthetic outcomes, some early studies suggest that matrix reconstruction may result in increased complication rates among patients.\textsuperscript{18} Meanwhile, many investigations have found no correlation between postoperative complications and acellular dermal matrix use.\textsuperscript{33} Despite these conflicting reports, a variety of acellular dermal matrix preparations have been developed by manufacturers.

| Table 2. Overview of Postoperative Complications |
|-----------------------------------------------|
| **Outcome** | **By Patient (%)** | **By Breast (%)** |
| Infection | 11 (4.7) | 12 (3.1) |
| Seroma | 37 (15.9) | 43 (10.9) |
| Hematoma | 9 (3.9) | 16 (4.1) |
| Delayed wound healing | 13 (5.6) | 19 (4.8) |
| Explantation | 15 (6.4) | 21 (5.3) |

| Table 3. Comparison of Clinical Outcomes between the Use of AlloDerm and FlexHD |
|-----------------------------------------------|
| **Outcome** | **By Patient** | **By Breast** |
| | **AlloDerm (%)** | **FlexHD (%)** | **p** | **AlloDerm (%)** | **FlexHD (%)** | **p** |
| Infection | 6 (4.6) | 5 (5.0) | 0.89 | 7 (3.1) | 5 (2.9) | 0.92 |
| Seroma | 23 (17.4) | 14 (13.9) | 0.46 | 28 (12.5) | 15 (8.8) | 0.25 |
| Hematoma | 4 (3.0) | 5 (5.0) | 0.45 | 9 (4.0) | 7 (4.1) | 0.96 |
| Delayed wound healing | 7 (5.3) | 6 (5.9) | 0.83 | 10 (4.5) | 9 (5.3) | 0.70 |
| Explantation | 7 (5.3) | 8 (7.9) | 0.42 | 10 (4.5) | 11 (6.5) | 0.38 |

| Table 4. Result of Binomial Regression Model for Infection |
|-----------------------------------------------|
| **Covariate** | **OR (95% CI), by Patient** | **p** | **OR (95% CI), by Breast** | **p** |
| AlloDerm vs. FlexHD | 0.69 (0.17–2.56) | 0.56 | 0.78 (0.22–2.72) | 0.69 |
| Age | 0.98 (0.92–1.05) | 0.62 | 0.99 (0.93–1.06) | 0.74 |
| BMI | 1.04 (0.91–1.20) | 0.55 | 1.07 (0.95–1.21) | 0.28 |
| History of smoking | 0.21 (0.05–0.88) | 0.033* | 0.17 (0.04–0.70) | 0.014* |
| Implant size | 1.48 (0.78–2.31) | 0.23 | 1.25 (0.70–2.23) | 0.45 |
| Radiation | 0.40 (0.09–2.72) | 0.41 | 0.40 (0.08–2.01) | 0.27 |
| Chemotherapy | 1.48 (0.25–8.83) | 0.12 | 1.59 (0.30–8.40) | 0.59 |

BMI, body mass index.

*Statistically significant (\( p < 0.05 \)). Binomial regression of odds of infection vs. no infection, controlling for potential confounding factors.
Few studies have been conducted that compare the outcomes across competing brands of acellular dermal matrix. In a recently published retrospective study (n = 309), Ranganathan et al. reported that a significantly higher proportion of patients who received FlexHD developed infection compared with AlloDerm (17.7 percent versus 8.1 percent, respectively; p = 0.039).25 Conversely, another study (n = 255), by Seth et al., indicated that the rate of infection for AlloDerm-based reconstruction was nearly double that of FlexHD; however, the variation in infection rate was not found to be statistically significant.28 A number of factors may have contributed to the disparity in complication rates between the two studies, most notably the differences in surgeon variables. In fact, in the study by Ranganathan et al., the authors submitted that the type of acellular dermal matrix used varied with the surgeon, but did not control for it in their study. If the type of acellular dermal matrix used was always correlated with a particular surgeon as the authors noted in their report, it stands to reason that the difference in infection rate detected in the study by Ranganathan et al. then also correlated to the surgeon, a confounding factor that cannot be adequately controlled for by any statistical method.

Previously, we demonstrated the importance of surgeon factors in patient outcomes after breast reconstruction. Surgeon teams (surgical oncologist and plastic surgeon pairs) that performed more cases together were associated with better outcomes, compared with the same plastic surgeons paired with surgical oncologists that they worked with less frequently.24 On examination of both patient and surgeon factors in their analysis, Ganske et al. suggest that complication rates following acellular dermal matrix reconstruction are inversely proportional to the surgeon’s experience.25 Furthermore, variance in surgical technique and product preference may contribute to the differences in outcome endpoints. Therefore, it is reasonable to conclude that accounting for surgeons as variables is essential to ascertain the relationship between type of acellular dermal matrix used and outcome.

This study uniquely reports an acellular dermal matrix comparison where the surgeon factor is adequately controlled, as the patients were treated by a single plastic surgeon and a very small cadre of surgical oncologists. Although internal variability in surgeon experience may have existed during the interval of observation, the frequency of postoperative complications does not suggest that the surgeon experienced a learning curve. Rather, an analysis of infection by case volume indicated that approximately half of the recorded infections occurred within the latter 105 procedures (45.1 percent), at which point the surgeon had nearly 4 years of experience in acellular dermal matrix–based breast reconstruction. As depicted in Figure 2, there exists a linear relationship between the cumulative incidence of infection and the volume of acellular dermal matrix–based breast reconstruction procedures (R² = 0.96). Therefore, we could not identify a predisposition for complications early in the surgeon’s career, which demonstrates that this surgeon’s results are consistent throughout the 6-year study period, which would not bias the study whether the type of acellular dermal matrix used varied over time.

Subgroup analysis of patients who experienced explantation revealed surgical-site infection

| Table 5. Odds Ratio for Postoperative Complication by Acellular Dermal Matrix Type (AlloDerm versus FlexHD)* |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Complication | OR (95% CI), by Patient | p | OR (95% CI), by Breast | p |
| Infection | 0.69 (0.17–2.56) | 0.56 | 0.78 (0.22–2.72) | 0.69 |
| Seroma | 1.17 (0.56–2.46) | 0.68 | 1.29 (0.65–1.05) | 0.47 |
| Hematoma | 0.61 (0.15–2.47) | 0.49 | 0.99 (0.35–2.83) | 0.99 |
| Delayed wound healing | 0.88 (0.28–2.74) | 0.82 | 0.85 (0.35–2.11) | 0.70 |
| Explantation | 0.48 (0.15–1.47) | 0.20 | 0.52 (0.21–1.33) | 0.17 |

*Binomial regression of odds of postoperative complication versus none for acellular dermal matrix type.

| Table 6. Systematic Analysis of Available Literature, by Breast |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Reference | No. FlexHD Breasts | FlexHD Infection Rate (%) | No. AlloDerm Breasts | AlloDerm Infection Rate (%) |
| Brooke et al., 201229 | 38 | 10.0 | 29 | 10.0 |
| Seth et al., 201328 | 233 | 5.2 | 136 | 10.3 |
| Liu et al., 201427 | 136 | 5.2 | 165 | 8.5 |
| Ranganathan et al., 201525 | 215 | 12.7 | 206 | 5.3 |
| Palaia et al., 201526 | 424 | 9.2 | 179 | 11.2 |
and tissue necrosis to be the most common indicators of implant loss. Although the variance among explantation rates could be attributed to acellular dermal matrix use, it is more likely a result of surgeon or patient dissatisfaction with the outcome because of asymmetry, capsular contracture, or concern for need to proceed with more aggressive oncologic treatment, as a result of other confounding medical problems. Note that bilateral explantation was more common than unilateral explantation (80 percent), even if the indication for implant removal existed for only one of the two breasts. As a result, the reconstructive outcome of a single breast was not truly independent of the contralateral breast, which suggested a trend toward significance where one may not have existed. Therefore, it is reasonable to expect that patient-specific data are a more accurate representation of explantation between the two groups, whereas for other outcomes that may be more breast-specific than patient-specific, data both by breast and by patient were analyzed. As indicated in Table 5, no significant differences exist in postoperative complications rates between AlloDerm and FlexHD.

The main limitation of this study is its retrospective nature. Examination occurred at a single institution, which could introduce selection bias. In addition, it is difficult to establish external validity, as surgeons at other institutions may prefer different reconstruction modalities. Procedural details were not included, as recall bias and changing methodologies present difficulties in retrospective analysis. The number of patients included in the study was limited by the surgeon’s caseload. Within the interval of observation, the surgeon was able to conduct a high volume of cases (>200 procedures). To avoid confounders of subgroup analysis, we did not break down the patient characteristics to determine whether the mastectomy was a nipple-sparing or a skin-sparing procedure, or the lymph node status. The majority (>70 percent) of mastectomies performed at our institution are nipple-sparing procedures, and the typical patient would have had a sentinel node biopsy but not an axillary dissection. Despite these limitations, the results of this study are generalizable across surgeons who are experienced in acellular dermal matrix breast reconstruction and provide important insights for future work. Higher level evidence would be produced if this study were to be repeated in a multi-institutional, randomized, prospective trial. Meanwhile, we may be better off directing efforts toward innovating fundamentally better approaches or mitigating other treatment factors associated with adverse outcomes.

The strength of this study is that it controls for surgeon factors and practice behaviors in the comparison of AlloDerm and FlexHD. The only confounding factor that contributed to a higher rate of infection by patient and by breast was a history of smoking. Therefore, our study confirms a known predictor of infection. Numerous studies
have reported that body mass index and history of radiation therapy increase the risk of infection, but these two factors were not covariates in our cohort. An association between body mass index and infection rate was not observed in the present study because our population was non-obese, with an average body mass index of 25 ± 5.3 kg/m², whereas infection correlates with obesity (body mass index >30 kg/m²). In addition, the cohort had a high rate of radiation therapy (postmastectomy radiation therapy) (30.5 percent) and, although the patients with infections presented with a slightly higher rate of postmastectomy radiation therapy, statistical significance was not achieved because of the small sample size. We observed that infection rate did not vary between acellular dermal matrix types. The present case series was performed by a single surgeon who used both acellular dermal matrix types throughout the study period, thereby controlling for variability in technique and product bias. As such, the lack of difference in infection rates between AlloDerm and FlexHD in the present study fails to document an inherent tendency for complication by either acellular dermal matrix type. In this regard, we believe that AlloDerm and FlexHD are equivalent. Therefore, the choice of acellular dermal matrix material should remain the surgeon’s preference.

CONCLUSIONS

No statistical difference in infection rate or any other clinical endpoint was observed between AlloDerm and FlexHD in immediate implant-based breast reconstruction. It is more likely that patient factors such as smoking and radiation therapy, and surgeon variables contributing to mastectomy skin flap quality, are more important to breast reconstruction outcomes. A multi-institutional, prospective, randomized, controlled trial is warranted to further investigate complications following matrix-based breast reconstruction, to overcome the inherent limitations of the retrospective studies in the literature and presented herein.

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