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# Complication prevalence following use of tutoplast-derived human acellular dermal matrix in prosthetic breast reconstruction: A retrospective review of 203 patients

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## KEYWORDS

Breast reconstruction;  
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**Summary** Use of human acellular dermal matrix (ADM) during prosthetic breast reconstruction has increased. Several ADM products are available produced by differing manufacturing techniques. It is not known if outcomes vary with different products. This study reports the complication prevalence following use of a tutoplast-derived ADM (T-ADM) in prosthetic breast reconstruction. We performed a retrospective chart review of 203 patients (mean follow-up times 12.2 months) who underwent mastectomy and immediate prosthetic breast reconstruction utilizing T-ADM, recording demographic data, surgical indications and complication (infection, seroma, hematoma, wound healing exceeding three weeks and reconstruction failure). During a four-year period, 348 breast reconstructions were performed. Complications occurred in 16.4% of reconstructed breasts. Infection occurred in 6.6% of breast reconstructions (3.7% – major infection, requiring intravenous antibiotics and 2.9% minor infection, requiring oral antibiotics only). Seromas occurred in 3.4% and reconstruction failure occurred in 0.6% of breast reconstructions. Analysis suggested that complication prevalence was significantly higher in patients with a BMI >30 ( $p = 0.03$ ). The complication profile following T-ADM use in this series is comparable to that reported for with other ADM products. T-ADM appears to be a safe and acceptable option for use in ADM-assisted breast reconstruction.

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## Introduction

The percentage of mastectomy patients who receive a prosthetic breast reconstruction is between 15 and 30%.<sup>1,2</sup> Implant-based reconstruction remains the most common reconstructive technique.<sup>3</sup> To improve clinical outcomes of prosthetic breast reconstruction, there has been an increased use of acellular dermal matrix (ADM). The reported benefits of ADM include: facilitating implant positioning in immediate or delayed reconstruction, simplified two-stage tissue expander-implant (TE/I) reconstruction,<sup>4,5</sup> improved control of the inframammary fold (IMF) and lower-pole fullness, shortened or eliminated need for subsequent tissue expansion, and increased options for direct-to-implant (DTI) or "one-stage" reconstruction.<sup>6</sup>

A major concern regarding ADM use in breast reconstruction is the potential for increased complications. Single institution reports provide conflicting information<sup>7–9</sup> and recent meta-analyses<sup>10–13</sup> suggest that prevalence of complication of ADM is increased though no particular ADM products were specified. An understanding of the prevalence of infection, and the outcomes of patients receiving post-mastectomy radiation therapy (PMRT) following ADM implantation are useful as these events may impact results<sup>7,14</sup> [See also, Table 1]. Several dermal matrix products are available<sup>15–21</sup> and questions exist as to the impact of differing product manufacturing techniques upon the product performance and patient outcomes.<sup>22</sup> The most studied ADM is AlloDerm (LifeCell Corp, Branchburg, NJ), an aseptically produced dermal matrix product, other ADM products have been less well studied.<sup>15–22</sup>

AlloMax™ Surgical Graft (C. R. Bard/Davol Inc, Warwick, RI), is a human derived ADM which undergoes the TutoPlast® Process preparation, of solvent dehydration cleaning and preservation process.<sup>22</sup> This yields a sterile and virally inactivated, rather than aseptic, product.

We report the prevalence of post-implant complications following use of Tutoplast-derived ADM (T-ADM) in prosthetic breast reconstruction, and the complication profiles of two different ADM recipient patient populations based on indication for surgery: risk-reduction versus oncologic presentation. Further, we compare these results to reports made of patients implanted with aseptically-prepared ADM.

## Patients and methods

The Institutional Review Board at NorthShore University HealthSystem approved this retrospective review of all patients undergoing immediate breast reconstruction using T-ADM-assisted two-stage (tissue-expander/implant) or one-stage (direct-to-implant) technique between January 2007 and December 2010. TutoPlast® processed human dermis (RTI Biologics™, Alachua, FL) was utilized, initially under the trade name NeoForm™ (Mentor Corp, Santa Barbara, CA) and subsequently under the trade name AlloMax™ due to a change in commercial licensing. Fellowship-trained surgical oncologists performed all mastectomies and board-certified plastic surgeons performed all reconstructions in a single academic healthcare system.

The method of T-ADM reconstruction was identical to that described by others<sup>5,6</sup> in order to create a defined inframammary fold and a stable pocket for placement of the expander/implant. After completion of the mastectomy, the breast skin flaps were inspected for adequate vascularity and hemostasis. The pectoralis major muscle was elevated from the chest wall and its costal origins, creating a submuscular pocket in the upper portion of the reconstruction. To cover the lower pole of the implant, allograft was hydrated and sutured to the chest wall, in a curvilinear path along the planned internal IMF. The leading edge of allograft was sutured to the inferior edge of the pectoralis. The implant (a tissue expander in two-stage reconstructions or a smooth round saline sizer in one-stage reconstructions) was placed in the space and the pocket closed temporarily to ensure correct device size. In one-stage reconstructions, the sizer was removed and the final implant placed into the pocket. The skin was sutured closed over a drain. Patients were prescribed prophylactic oral antibiotics until the drains were removed once drainage was consistently 30 cc or less per drain in a 24 h period.

Chart review abstracted age, patient co-morbidities (including history of radiation and chemotherapy), surgical procedure type, and occurrence of complications, independently assessed by two investigators (VLMR and RTB). When there was lack of consensus, the chart was reviewed by a third investigator (MAH). The outcome data were analyzed for specific patient risk factors and associated complications. Identified complications were: infection, hematoma, seroma (a loculated, symptomatic fluid collection requiring aspiration or drain placement), flap loss, delayed wound healing (wounds lasting >3 weeks) and reconstruction failure (implant removal). Infection was defined as 'major' if intravenous antibiotics, hospitalization, and/or surgical debridement were required and 'minor' if oral antibiotic therapy alone was used.

We defined "risk-reduction" as mastectomy performed for a patient who did not have an active cancer diagnosis (eg. BRCA+ or had completed all treatments for the breast cancer). An "oncologic" patient indication included mastectomy performed for treatment of an active breast cancer and a contralateral mastectomy for risk-reduction). These patients have different therapeutic profiles, which may influence complications. As such the data is reported in aggregate, and also following segregation. The prevalence of complications is reported as both per patient (PP) and per reconstruction (PR) to facilitate comparison with prior studies.

Data were analyzed using SPSS 15.0, (IBM Corp., Chicago, IL). Continuous data such as age (at time of mastectomy) and length of follow-up (in months) were reported as mean (SD) while categorical data such as surgical procedure type and occurrence of complications were reported as count and percentage. Student's *T*-test (for continuous variables) and chi-square or Fisher exact tests (for categorical variables) were used to determine the significance of difference between risk-reduction and oncologic patients. We conducted univariate and multivariate logistic regression analyses to determine the independent risk factors of postoperative complications. For each analysis, preoperative (patient demographics and co-

**Table 1** Previous studies reporting complications in breast reconstruction facilitated by ADM use.

| Author                               | Type                              | <i>n</i>   | Overall complications (%)                                | Infection (%)   | Seroma (%)  | Radiation Hx                                      | No radiation                                       |
|--------------------------------------|-----------------------------------|--|--|---|---|---|--|
| Antony, 2010 <sup>25</sup>           | 2 stage reconstruction            | 96 women 153 breasts   | (23.6)   | (7.2)   | (7.2)   | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Bindingnavale, 2007 <sup>26</sup>    | 2 stage reconstruction            | 41 women 65 breasts  | 7/65 (10.8)  | 2/65 (3.1)  | 3/65 (4.6)  | 1/5 (20)  | 6/41 (14.7) <sup>a</sup>                           |
| Brooke, 2012 <sup>18</sup>           | Mostly 2 stage reconstruction     | 29 women 49 breasts  | 11/49 (22)   | 5/49 (10)   | <sup>a</sup>  | <sup>a</sup>                                      | <sup>a</sup>                                       |
| <i>AlloDerm</i>                      |                                   | 64 women 110 breasts   | 16/110 (15)  | 11/110 (10)   | <sup>a</sup>  | <sup>a</sup>                                      | <sup>a</sup>                                       |
| <i>DermaMatrix</i>                   |                                   | 38 women 62 breasts  | 10/62 (16)   | 6/62 (10)   | <sup>a</sup>  | <sup>a</sup>                                      | <sup>a</sup>                                       |
| <i>Flex HD</i>                       |                                   | 11 women 13 breasts  | 1/11 (9.0)   | 1/11 (9.0)  | 1/11 (9.0)  | 0/2 (0)   | 1/9 (11)   |
| Gamboa-Bobadilla, 2006 <sup>27</sup> | single and 2-stage reconstruction | 119 women 75 breasts <sup>b</sup>  | 17/75 (22.7) <sup>b</sup>                                | 9/75 (12.0) <sup>b</sup>                              | 5/75 (6.7) <sup>b</sup>                               | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Lanier, 2010 <sup>8</sup>            | 2 stage reconstruction            | 52 breasts <sup>b</sup>  | 24/52 (46.2) <sup>c</sup>                                | 15/52 (28.9) <sup>c</sup>                             | 8/52 (15.4) <sup>c</sup>                              | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Liu, 2011 <sup>9</sup>               | Mostly 2 stage reconstruction     | 151 women <sup>b</sup><br>204 breasts <sup>b</sup><br>192 women <sup>c</sup><br>266 breasts <sup>c</sup> | 25/204 (12.3) <sup>b</sup><br>52/266 (19.5) <sup>c</sup> | 5/204 (2.5) <sup>b</sup><br>18/266 (6.8) <sup>c</sup> | 8/204 (3.9) <sup>b</sup><br>19/266 (7.1) <sup>c</sup> | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Losken, 2008 <sup>20</sup>           | Mostly 2 stage reconstruction     | 22 women 31 breasts  | 1/31 (3.2)   | 0/31 (0)  | 0/31 (0)  | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Nahabedian, 2009 <sup>7</sup>        | 2 stage reconstruction            | 285 women <sup>b</sup><br>376 breasts <sup>b</sup><br>76 women <sup>c</sup><br>100 breasts <sup>c</sup>  | (~11.0) <sup>b</sup> 17/100 (17.0) <sup>c</sup>          | 22/376 (5.9) <sup>b</sup><br>5/100 (5.0) <sup>c</sup> | 9/376 (2.4) <sup>b</sup><br>5/100 (5.0) <sup>c</sup>  | Not reported for non-ADM 8/23 (34.7) <sup>c</sup> | Not reported for non-ADM 10/77 (13.0) <sup>c</sup> |
| Nguyen, 2010 <sup>23</sup>           | 2 stage reconstruction            | 163 women <sup>b</sup><br>246 breasts <sup>b</sup><br>41 women <sup>c</sup><br>76 breasts <sup>c</sup>   | 11/246 (4.5) <sup>b</sup><br>10/75 (13.3) <sup>c</sup>   | 7/246 (2.8) <sup>b</sup><br>4/75 (5.3) <sup>c</sup>   | <sup>a</sup>  | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Salzberg, 2011 <sup>14</sup>         | Single stage reconstruction       | 260 women 466 breasts  | (3.9)  | 1/466 (0.4)   | <sup>a</sup>  | 3/21 (14.3)                                       | 15/445 (3.4)                                       |
| Seth, 2012 <sup>19</sup>             | 2-stage reconstruction            | 96 women 136 breasts   | 26/136 (19.1)  | 14/136 (10.3)   | 3/136 (2.2)   | <sup>a</sup>                                      | <sup>a</sup>                                       |
| <i>Cryopreserved ADM</i>             |                                   | 159 women 233 breasts  | 45/233 (19.3)  | 12/233 (5.2)  | 5/233 (2.1)   | <sup>a</sup>                                      | <sup>a</sup>                                       |
| <i>Pre-hydrated ADM</i>              |                                   | 43 women 58 breasts  | 7/58 (12)  | 4/58 (6.9)  | 1/58 (1.7)  | 5/11 (45)   | 2/47 (4.3)   |
| Spear, 2008 <sup>15</sup>            | 2 stage reconstruction            | 58 women 90 breasts  | <sup>a</sup>   | 18 (20)   | 4 (4.4)   | <sup>a</sup>                                      | <sup>a</sup>                                       |
| Weichman, 2013 <sup>17</sup>         | 1- and 2-stage reconstruction     | 64 women 105 breasts   | <sup>a</sup>   | 9 (8.5)   | 1 (1.0)   | <sup>a</sup>                                      | <sup>a</sup>                                       |
| <i>Ready-to-use ADM</i>              |                                   |  |  |   |   |   |  |

<sup>a</sup> Unable to determine completely due to lack of data.

<sup>b</sup> No ADM usage in this population.

<sup>c</sup> ADM used in this population.

morbidities) and intra-operative (surgical procedure and reconstruction types) variables showing an association with postoperative complications at  $p < 0.1$  in the univariate analysis were included in the multivariate logistic regression models. Significance is reported for  $p$ -values less than 0.05.

## Results

During the four-year study window, 348 immediate prosthetic breast reconstructions were performed in 203 patients. In 136 patients, the primary indication was for oncologic treatment while 67 patients were for risk

reduction. Mean patient age was 48.5 years at the time of first surgery. The mean length of follow-up was 12.1 months [Range: 0.2–26.2 months; Median: 10.9 months]. Patient demographics are shown in Table 2.

Risk-reducing patients had significantly lower rates of both radiation and chemotherapy as compared with oncology-present patients. The delivery for these treatments was also different. In risk-reducing patients radiation and chemotherapy were mostly administered pre-operatively, while oncologic patients received radiation and chemotherapy at more variable intervals. On the whole, risk-reducing patients had a higher rate of nipple-sparing mastectomy and bilateral procedures (Tables 3 and 4).

There were 57 complications in the total study population with complications occurring in 28.1% of patients and 16.4% of reconstructed breasts. The most common complication was infection. Major infections (Per Patient: 6.4%; Per Reconstruction: 3.7%) required IV antibiotic therapy or re-operation (including graft removal in two patients) while minor infections (PP: 4.9%; PR: 2.9%) resolved with oral antibiotics alone. Next most common complications were seroma and wound healing greater than 3 weeks, which had identical rates (PP: 5.9% PR: 3.4%). Hematoma, mastectomy flap loss and reconstruction failure occurred far less frequently. There was no statistical differences in complications between the risk reducing and oncologic patients.

Analysis suggested that elevated BMI (OR = 1.07, 95% CI 1.01–1.13,  $p = 0.03$ ) was associated with higher risk of post-operative complications. However, with multivariable analysis after controlling for age and reconstruction type, BMI was no longer statistically significant.

There were too few instances of radiation or chemotherapy in the risk reducing population to compare with the oncologic population. Within the oncologic patients, there was no significant interaction between complication occurrence and either radiation or chemotherapy. Likewise, history of smoking, diabetes, and alcohol usage were not correlated with increased complications in either group.

## Discussion

We examined our complications following use of Tutoplast-derived acellular dermal matrix (T-ADM) used with prosthetic breast reconstruction. Following 348 placements of T-ADM in 203 patients, complications (infection, seroma, hematoma, or delayed wound healing) occurred in 16.4% of breast reconstructions. Infection, which may lead to explantation and “reconstruction failure” occurred in 6.6% of T-ADM breast reconstructions. We divided infection into major and minor infection based on the severity of presentation and treatment required. Major infection was defined as requiring surgical management or IV antibiotics

**Table 2** Population demographics reported as mean (SD) or prevalence (percentage).

|                                     | Risk-reduction only (N = 67) | Oncologic Hx (N = 136) | p Value             |
|-------------------------------------|------------------------------|------------------------|---------------------|
| Age (in years at time of surgery)   | 42.0 (10.1)                  | 51.9 (10.5)            | <0.00 <sup>b</sup>  |
| Length of follow-up (months)        | 11.1 (7.9)                   | 12.6 (7.3)             | 0.170               |
| Median length of follow-up (months) | 9.8                          | 11.3                   |                     |
| Range length of follow-up (months)  | 0.2–28                       | 0.2–26.2               |                     |
| BMI ± SD                            | 22.7 (4.0)                   | 24.8 (5.3)             | 0.004 <sup>b</sup>  |
| Co-morbidities <sup>d</sup>         |                              |                        |                     |
| Diabetes mellitus                   | 1 (1.5%)                     | 11 (8.1%)              | 0.109               |
| Tobacco use (current)               | 2 (2.9%)                     | 6 (4.4%)               | 1.000               |
| Tobacco use (former)                | 17 (25.3%)                   | 31 (22.8%)             | 0.862               |
| Alcohol use (occasional)            | 50 (74.6%)                   | 95 (69.9%)             | 0.480               |
| Risk/markers                        |                              |                        |                     |
| Positive family history             | 26 (38.8%)                   | 36 (26.5%)             | 0.077               |
| BRCA+                               | 36 (53.4%)                   | 15 (11.0%)             | <0.001 <sup>c</sup> |
| Adjuvant therapy                    |                              |                        |                     |
| Radiation                           | 2 (2.9%)                     | 37 (27.2%)             | <0.001 <sup>c</sup> |
| Chemotherapy                        | 4 (6.0%)                     | 65 (47.8%)             | <0.001 <sup>c</sup> |
| Number of procedures <sup>a</sup>   | 132                          | 216                    |                     |
| Total mastectomy                    | 57 (43%)                     | 155 (72%)              | <0.001 <sup>c</sup> |
| Modified radical mastectomy         | 0                            | 16 (7%)                |                     |
| Nipple-sparing mastectomy           | 75 (57%)                     | 45 (21%)               |                     |
| Reconstructions <sup>a</sup>        | 132                          | 216                    |                     |
| One-stage                           | 109 (83%)                    | 108 (50%)              | <0.001 <sup>c</sup> |
| Two-stage                           | 23 (17%)                     | 108 (50%)              |                     |

<sup>a</sup> Reflects the number of breasts treated by each type of mastectomy procedure.

<sup>b</sup>  $p$  is significant as measured by  $t$ -Test.

<sup>c</sup>  $p$  is significant as measured by Pearson  $\chi^2$ .

<sup>d</sup> Patient can have multiple co-morbidities.

**Table 3** Complications observed in patients with Allomax-assisted breast reconstruction patients. Total cohort, and separated based on presence of malignancy.

|                        | Events | Incidence<br>(% per<br>patient) <sup>a</sup> | Incidence<br>(% per<br>reconstruction) <sup>b</sup> | Events in<br>risk-reducing<br>cases (% of<br>reconstructions) <sup>c</sup> | Events in oncologic<br>cases (% of<br>reconstructions) <sup>d</sup> | Odds<br>ratio | 95% CI    | <i>p</i> Value |
|------------------------|--------|--|---|--|---|---------------|-----------|----------------|
| Seroma                 | 12     | 5.9  | 3.4   | 4 (3.0)  | 8 (3.7)   | 1.23          | 0.36–4.17 | 0.78           |
| Hematoma               | 4      | 2.0  | 1.1   | 1 (0.8)  | 3 (1.4)   | 1.84          | 0.19–17.9 | 1.00           |
| Infection—Major        | 13     | 6.4  | 3.7   | 3 (2.3)  | 10 (4.6)  | 2.09          | 0.57–7.7  | 0.38           |
| Infection—Minor        | 10     | 4.9  | 2.9   | 2 (1.5)  | 8 (3.7)   | 2.5           | 0.52–12.0 | 0.33           |
| Delayed wound healing  | 12     | 5.9  | 3.4   | 7 (5.3)  | 5 (2.3)   | 0.42          | 0.13–1.36 | 0.22           |
| Mastectomy flap loss   | 4      | 2.0  | 1.1   | 0.0  | 4 (1.9)   | inf           | inf       | 0.17           |
| Reconstruction failure | 2      | 1.0  | 0.6   | 0.0  | 2 (0.9)   | inf           | inf       | 0.53           |
| Total                  | 57     | 28.1   | 16.4  | 17 (12.9)  | 40 (18.5)   | 1.59          | 0.86–2.9  | 0.14           |

<sup>a</sup> Total number of patients in this population is 203.

<sup>b</sup> Total number of reconstructions in this population is 348.

<sup>c</sup> Total number of reconstructions in this population is 132.

<sup>d</sup> Total number of reconstructions in this population is 216.

and/or further surgical management occurred in 3.7% of breast reconstructions. This differs from others studies that report infection without describing severity<sup>8</sup> or those who specify cases which require IV antibiotics or explantation.<sup>14,18,23</sup> Further, the overall infection occurrence in this series was lower<sup>17–19</sup> or comparable<sup>7,9,15,23</sup> to other reported series. Of the thirteen major infections, nine were cellulitis with no documented pathogen, and one each of candida parapsilosis, pseudomonas, staphylococcus, and MRSA. No minor infection patient had a positive culture, nor did any have reconstruction failure. Thus, some of these may represent seroma or inflammatory response to the T-ADM, commonly referred to as “the red breast syndrome”. Hence, the true prevalence of infection may be closer to that of the major infection prevalence of 3.9% and suggests that the T-ADM infection profile is similar to others previously reported.<sup>8,18</sup> Recently, Weichman and colleagues<sup>17</sup> compared reconstructions with ready-to-use versus aseptic acellular dermal matrix, and while they found a decrease in overall infection (8.5 percent versus 20.0 percent;  $p = 0.0088$ ), they found no statistically significant difference in either major infection (4.7 percent versus 12.2 percent;  $p = 0.069$ ), or need for explantation (1.9 percent versus 6.6 percent;  $p = 0.1470$ ) between their groups.

The prevalence of complications and infections in our series is similar to reports of alternative ADM products<sup>7,21</sup> as well as the meta-analyses of ADM-assisted breast reconstruction reports.<sup>10,15</sup> Kim et al.<sup>10</sup> found a 15.4% overall prevalence of surgical complications and an increase in the pooled risk of infection from 4.7% (no ADM implant reconstruction) to 5.3% (with ADM) and a relative risk of infection with ADM of 2.47 (95% confidence interval, 1.71–3.57) compared to no ADM. Likewise, Newman et al.<sup>12</sup> reported 12% overall prevalence of complications with infection (5.6%) and seroma (3.3%) being the most frequent complications. We have no definitive reason explanation for the lower prevalence of complications in one-stage versus two-stage reconstruction cohorts. However, this may be due to selection bias as patients undergoing one-stage reconstruction were required to be healthy and smaller-breasted.

Our univariate analysis suggested that patients with elevated BMI had increased complications, similar to studies of aseptic-ADM.<sup>9</sup> We did not find an association between tobacco use (either former or current) with increased complications. However, the prevalence of smoking in our patient population (3.9% current, 23.7% former) may not be high enough to demonstrate an effect. Finally, we saw no impact of diabetes on complication

**Table 4** Univariate and multivariable logistic regression on any complications.

| Predictor                         | Univariate |           |                | Multivariable <sup>a</sup> |           |                |
|-----------------------------------|------------|-----------|----------------|----------------------------|-----------|----------------|
|                                   | OR         | 95%CI     | <i>p</i> value | OR                         | 95%CI     | <i>p</i> value |
| Risk-reducing vs. oncologic       | 0.82       | 0.42–1.58 | 0.547          | 1.38                       | 0.63–3.01 | 0.424          |
| Age (in years at time of surgery) | 1.03       | 0.99–1.05 | 0.063          | 1.02                       | 0.99–1.05 | 0.193          |
| BMI > 30 (kg/m <sup>2</sup> )     | 1.07       | 1.01–1.13 | 0.031          | 1.05                       | 0.99–1.12 | 0.101          |
| Type of mastectomy                |            |           |                |                            |           |                |
| Modified radical vs. total        | 0.72       | 0.19–2.76 | 0.628          | —                          | —         | —              |
| Nipple-sparing vs. total          | 0.86       | 0.44–1.67 | 0.656          | —                          | —         | —              |
| One-stage vs. two-stage           | 0.57       | 0.31–1.05 | 0.072          | 0.57                       | 0.29–1.10 | 0.095          |

<sup>a</sup> Variables with  $p < 0.1$  in the univariate analysis were included in the multivariable analysis. Patient population group (risk-reducing vs oncologic) was included in the multivariable as it is our main comparison of interest.

development in our study, but this may be because the percentage of diabetes patients in this population was less than 10%.

The effect of radiation therapy on the prevalence of complications is unsettled.<sup>14,15,23,24</sup> We did not find a higher prevalence of complications with radiation therapy. This finding could be due to the small population of radiated patients in the study and selection bias. We recognize the risk for complications may increase in previously irradiated patients. If previously irradiated patients have signs of radiation injury, (i.e.: substantial skin changes or tight skin/muscle envelope) we favor autologous reconstruction. Further, patients who undergo post mastectomy radiation generally do so following chemotherapy treatment weeks or months after initial mastectomy and allograft placement. Thus, one would expect the allograft to be fully incorporated and behave similarly to non-allograft, vascularized tissue. Our study was not designed to compare post-mastectomy radiation outcomes in allograft vs. total sub-muscular patient reconstruction populations.

The limitations of our study include it being an unmatched retrospective study with selection bias, our not evaluating aesthetic results, patient reported outcomes, or economics.

In conclusion, our use of Tutoplast-derived acellular dermal matrix in prosthetic breast reconstruction demonstrated similar complication prevalence to other ADM products used today. As such, this product can be considered when an ADM is needed with prosthetic breast reconstruction.

## Ethical approval

The Institutional Review Board at NorthShore University HealthSystem approved this study.

## Conflict of interest and funding statement

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