

# AlloDerm RTU Integration and Clinical Outcomes When Used for Reconstructive Breast Surgery

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**Background:** AlloDerm Ready To Use (RTU) is a sterile version of AlloDerm regenerative tissue matrix, developed in response to concerns regarding the potential risk of infectious complications with the latter aseptic matrix. Clinical data on AlloDerm RTU use is, however, limited, particularly with respect to histologic evidence of graft integration and clinical outcomes.

**Methods:** Consecutive patients who underwent tissue-expander/implant reconstruction with the use of AlloDerm RTU from March 2011 to September 2012 were included in this analysis. Biopsies of AlloDerm RTU/capsule interface were obtained at the time of expander/implant exchange and evaluated for evidence of cellularization, vascularization, and inflammatory reaction. Data on postoperative complications were retrieved from patient records.

**Results:** A total of 116 biopsy specimens from 68 patients were obtained. At biopsy, on visual inspection, nearly all grafts were fully integrated within the host tissue. Histologically, graft specimens demonstrated mild-to-moderate neovascularization and cellular repopulation with no inflammatory cells. All patients were followed for 5 years postoperatively. Short-term postoperative complications of skin necrosis, seroma, and infection occurred in 10.3%, 4.3%, and 2.6% of reconstructions, respectively. Capsular contracture (grade 3) was the only long-term complication (5.2%). Rates of short- and long-term complications are similar to those observed in our previous experience with AlloDerm reconstructive tissue matrix.

**Conclusions:** AlloDerm RTU used in breast reconstructive surgery fully integrates and incorporates into host tissue. There were no unexpected safety concerns with its use at short-term or at long-term, at least up to 5 years of follow-up. (*Plast Reconstr Surg Glob Open* 2018;6:e1744; doi: 10.1097/GOX.0000000000001744; Published online 18 May 2018.)

## INTRODUCTION

Acellular matrix has revolutionized implant-based breast reconstruction since its introduction in 2004 for breast reconstruction. At present, 65% of implant-based breast reconstructions are performed with the use of acellular matrix.<sup>1</sup> Typically, acellular matrix serves to reinforce the lower breast pocket and stabilize the implant or expander. In this capacity, it provides surgeons with an al-

ternative soft tissue option to recruiting adjacent muscles and fascia.<sup>2-5</sup> Over time, other benefits to its use have been realized, notably improving cosmetic outcome and reducing the risk of capsular contracture.<sup>6-9</sup>

Several acellular matrix products are currently available for use in breast reconstruction, including human-derived [FlexHD (Ethicon, Somerville, N.J.); AlloDerm Regenerative Tissue Matrix (RTM, LifeCell, Branchburg, N.J.), AlloDerm RTM Ready To Use (RTU, LifeCell, Branchburg, N.J.), Neoform (Mentor, Santa Barbara, Calif.), DermaMatrix (Synthes, West Chester, Pa.), and DermACELL (NOVADAQ, Bonita Springs, Fla.); porcine-derived (Permacol {Covidien, Boulder, Colo.} and Strattice {LifeCell, Branchburg, N.J.}); and bovine-derived (Surgimend {Integra, Plainsboro, N.J.})] matrices. In addition

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to the variability in the source, these products also vary with respect to processing. Consequently, variability in outcome is to be expected from their use. There is, however, limited data to guide their use with the exception of AlloDerm RTM, the first acellular matrix marketed for breast reconstruction. Even with AlloDerm RTM, variable outcomes have been reported, particularly with respect to rates of infection and seroma, with some studies reporting higher rates relative to total submuscular implant coverage.<sup>10–13</sup> Because AlloDerm RTM is aseptic and not sterile, there have been concerns that this could be a potential contributing factor to higher incidences of infection. To address this concern, a sterile version of this matrix, AlloDerm RTU, was introduced in 2011.

As a relatively new product, clinical data on AlloDerm RTU in breast reconstruction is limited.<sup>14–20</sup> This study was undertaken to report on the clinical performance of AlloDerm RTU in 2-stage, tissue expander/implant breast reconstruction, specifically with respect to histologic evidence of graft integration and clinical outcomes.

### PATIENTS AND METHODS

This retrospective, single-center, single-surgeon, cohort study enrolled consecutive patients who underwent 2-stage, tissue-expander/implant breast reconstruction with the use of AlloDerm RTU from March 2011 to September 2012. Patients who underwent revision breast reconstruction, breast aesthetic surgery, or a combination of expander and autologous tissue flap reconstruction were excluded. The study protocol was approved by PeaceHealth Southwest Medical Center Institutional Review Board (Vancouver, Wash.).

Following mastectomy for oncologic or prophylactic reasons, patients underwent immediate breast reconstruction with low- or moderate-height tissue expanders. AlloDerm RTU (8×16 cm) was prepared according to manufacturer’s instructions and positioned and sutured at the lower breast pole, as previously described for other acellular dermal matrix products.<sup>5,21–24</sup> Patients were discharged within 2–3 days and closely monitored for the development of postoperative complications at regular intervals. Typically, after 3 months of tissue expansion, patients’ expanders were exchanged for “permanent” implants. In patients who were scheduled to undergo postoperative radiotherapy or chemotherapy, expander exchange was delayed until completion of adjuvant treatment.

At the time of expander/implant exchange, punch biopsies of AlloDerm RTU/muscle-capsule interface were obtained from all patients. Specimens were immediately fixed in 10% neutral-buffered formalin and sent to an independent pathologist for processing and histopathologic examination. Processing involved dehydration through a graded series of reagent alcohol from 70% to 100%, clearing in xylene substitute, and embedding in paraffin. The paraffin blocks were sliced into 4- to 5-µm thick sections, mounted on standard glass microscope slides, and stained with Harris Hematoxylin and Eosin-Y and Verhoeff’s van Geison. Prepared sections were evaluated for presence/

absence and extent of cellularization (fibroblast density), vascularization (capillary density), and inflammatory reaction (inflammatory cell density). Cell and capillary density were scored semiquantitatively as none (absence of cells), mild, moderate, or significant. Clinical graft integration was evaluated qualitatively by gross observation. Presence of seroma and or loose AlloDerm RTU was taken as evidence for nonintegration of graft.

After each stage of breast reconstruction, all incidences of postoperative complications, including infection, skin necrosis/dehiscence, hematoma, seroma, expander/implant loss, and clinically significant capsular contracture (Baker grade 3 or 4) were assessed and recorded by the reconstructive surgeon (A.G.). Patient demographic information (age and body mass index), clinical characteristics (smoking status, hypertension, diabetes, and obesity), and neoadjuvant and/or adjuvant therapy use (preoperative and postoperative chemotherapy and/or radiation therapy) were obtained from patient records. The influence of these patient variables on outcomes was assessed.

### RESULTS

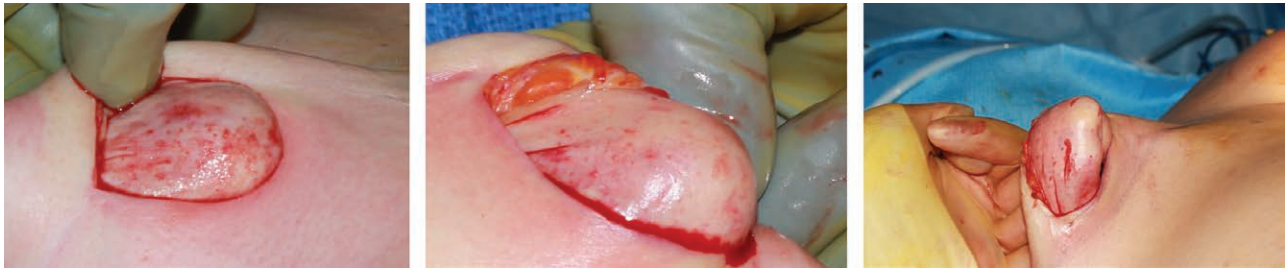
Sixty-eight patients who underwent AlloDerm RTU-assisted, immediate, tissue expander/implant reconstruction were included in this analysis. Forty-eight patients had bilateral and 20 patients had unilateral mastectomies. Sixty percentage of the mastectomies were nipple-sparing (Table 1). Patients had a mean age of 53 years. The majority of patients were relatively healthy, with a mean body mass index of 26 kg/m<sup>2</sup>. Twenty-two percentage of patients had comorbidities. Neoadjuvant/adjuvant therapy was prevalent, with 43% of patients having had chemotherapy and 17% radiotherapy.

One hundred sixteen AlloDerm RTU biopsy specimens were obtained, 1 from each breast, during expander/implant exchange. Specimens were obtained at a mean of 6.0±4.0 months from expander placement

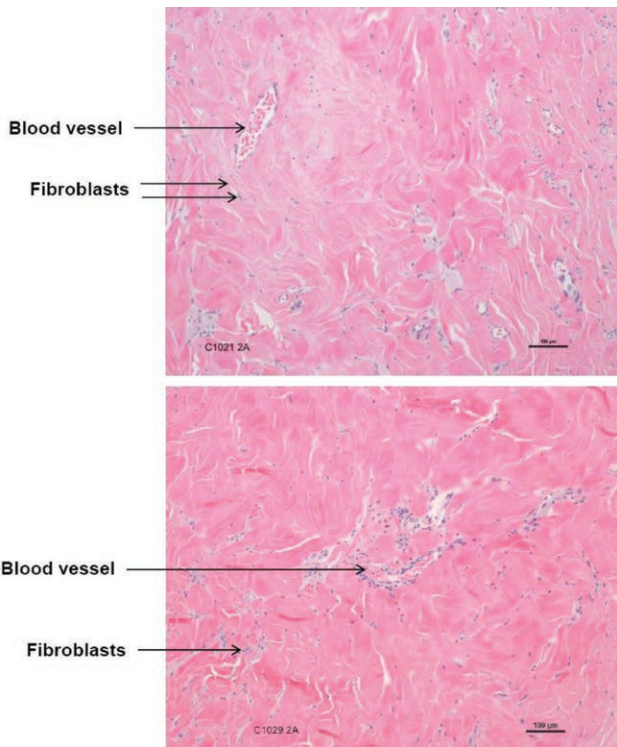
**Table 1. Patient Demographics, Comorbidities, and Chemo- and/or Radiotherapy**

|  |           |
|--|-----------|
| Patients, n  | 68        |
| Breasts, n   | 116       |
| Age (y)  |           |
| Mean   | 52.6      |
| Range  | 25–70     |
| Body mass index (kg/m <sup>2</sup> )                     |           |
| Mean   | 25.5±4.9  |
| Range  | 18.2–40.0 |
| Comorbidities, no. patients (%)                          | 15 (22.1) |
| Obesity*   | 13 (19.1) |
| Diabetes mellitus  | 2 (2.9)   |
| Type 1   | 1 (1.5)   |
| Type 2   | 1 (1.5)   |
| Nipple-sparing mastectomy, no. breast (%)                |           |
| Yes  | 70 (60.3) |
| No   | 46 (39.7) |
| Radiation, no. breast (%)                                | 20 (17.2) |
| Preoperative (percentage of irradiated breasts)          | 5 (25.0)  |
| Postoperative (percentage of irradiated breasts)         | 15 (75.0) |
| Chemotherapy, no. patients (%)                           | 29 (42.6) |
| Preoperative (percentage of patients with chemotherapy)  | 16 (55.2) |
| Postoperative (percentage of patients with chemotherapy) | 13 (44.8) |

\*Defined as ≥ 30 kg/m<sup>2</sup>.

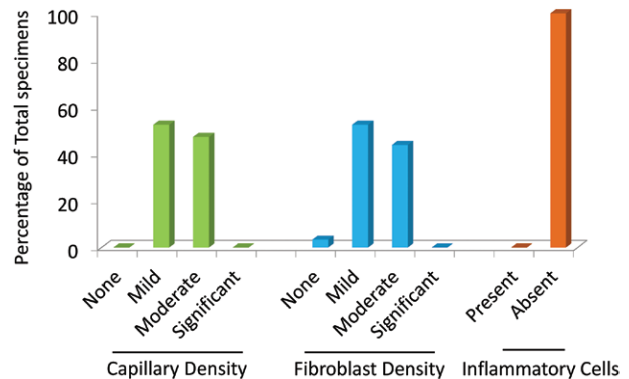


**Fig. 1.** Gross pathology of AlloDerm RTU during expander/implant exchange. Representative photographs depicting fully integrated AlloDerm RTU from 3 different patients. Photographs were taken at approximately 3 months after expander reconstruction.



**Fig. 2.** Cellular repopulation and vascularization of AlloDerm RTU. Graft biopsies were obtained at expander/implant exchange demonstrate a fully incorporated matrix with cellular (fibroblast) ingrowth and revascularization. Hematoxylin and Eosin staining, 200× magnification.

(range, 2.1–19.0 months). At the time of biopsy, on visual inspection, all grafts were fully integrated within the host tissue, with the exception of 1. Integrated grafts appeared healthy, had no signs of foreign body reaction (encapsulation, resorption, or contracture), and demonstrated punctate bleeding (Fig. 1). Gross graft integration was confirmed histologically. Graft specimens demonstrated mild-to-moderate neovascularization and cellular (fibroblasts) repopulation (Figs. 2, 3). Inflammatory cells were absent. At the graft/capsule interface, synovia-like metaplasia was observed within the capsule and absent within the graft (Fig. 4). Elastin staining revealed the demarcation of graft from capsular tissue, with the former showing an abundance and the latter showing an absence of elastin (Fig. 4).



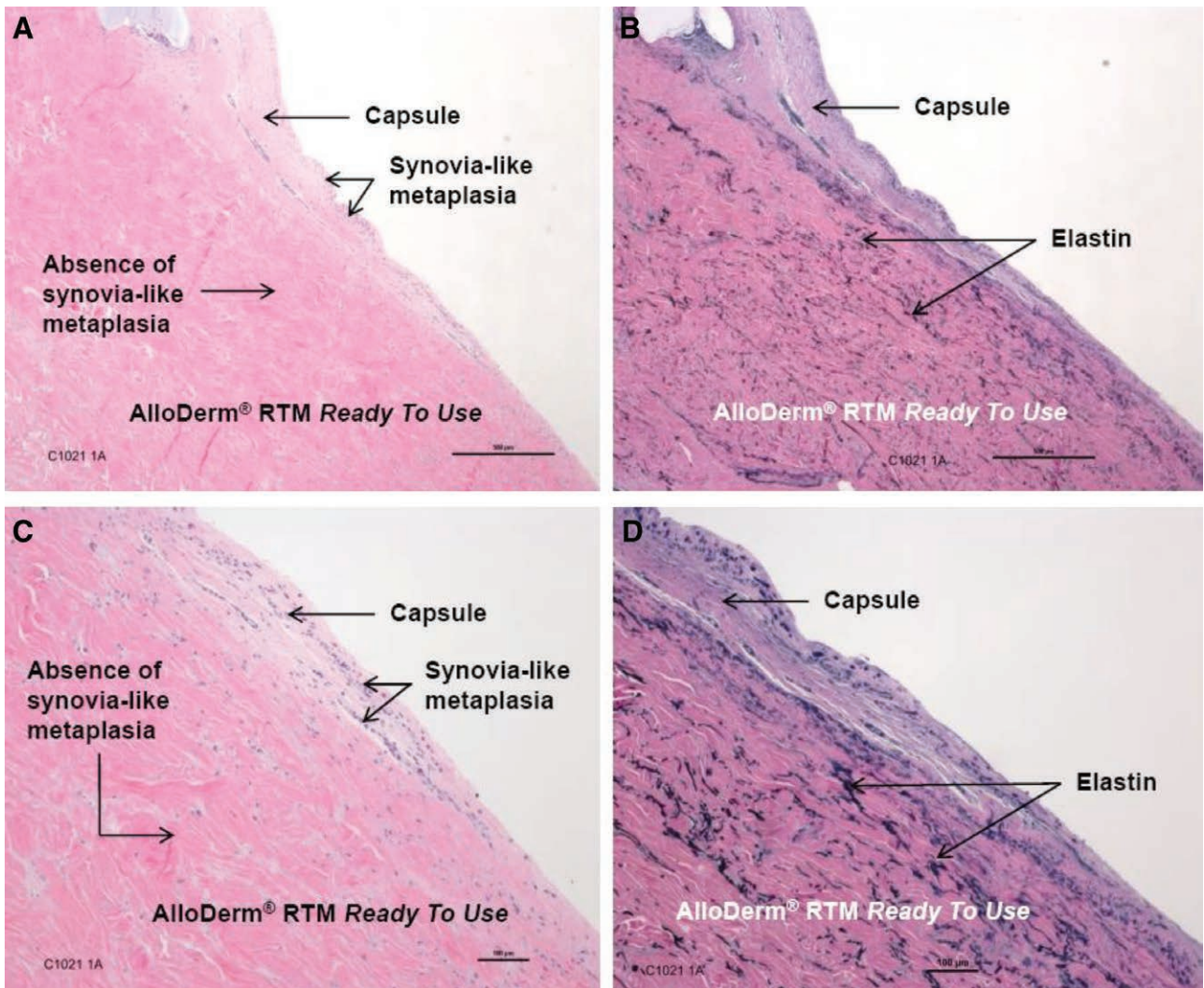
**Fig. 3.** Capillary and cellular density within AlloDerm RTU at expander/implant exchange. Density estimated from biopsy specimens.

In the 1 graft that was not fully integrated, pockets of loose unintegrated graft were noted. In the integrated portions of the graft, vascularization was noted, and interestingly, there was no evidence of inflammation or foreign body reaction. At expander/implant exchange, the unincorporated area was excised and the patient had an uneventful clinical course.

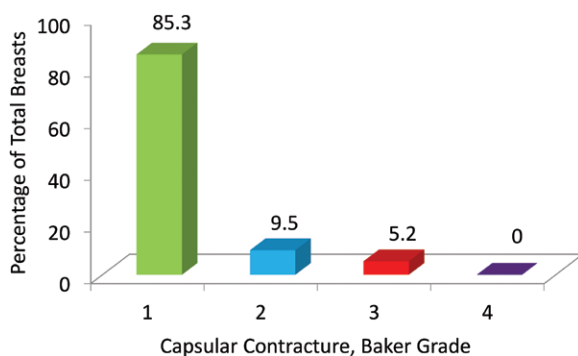
During expander/implant exchange, 16 implants in 8 patients were placed prepectoral. Plane conversion from subpectoral to prepectoral was undertaken in these patients because of complaints of pain and discomfort. Short-term postoperative complications of skin necrosis (12 cases) and seroma (5 cases) occurred in 10.3% and 4.3% of reconstructions, respectively. Three of the 5 cases of seroma (2.6%) had positive cultures, without visible signs of infection and were treated with intravenous antibiotics following seroma drainage. Four patients (7 breasts) died during follow-up due to their metastatic disease. Each of the remaining 64 patients was followed for 5 years postoperatively.

Long-term complications were limited to clinically significant capsular contracture (Baker grade 3) in 6 breasts (6 patients) for a capsular contracture rate of 5.2% (Fig. 5). Patients who had capsular contracture had no commodities, but 3 had radiotherapy (2 postoperatively and 1 preoperatively), 5 had chemotherapy (3 postoperatively and 2 preoperatively), and 2 had both radiotherapy and chemotherapy. On univariate analysis, only radiotherapy was significantly associated with the development of capsular contracture, while only chemotherapy, chemo- and radiotherapy, and no treatment (no chemo- and or





**Fig. 4.** AlloDerm RTU/capsule interface during expander/implant exchange. A and B, Demonstrates the absence of synovia-like metaplasia within the graft and its presence in the capsule. B and D, Demonstrates elastin within the graft and its absence within the capsule. A and B, Hematoxylin and eosin staining, 100× magnification. B, Hematoxylin and eosin staining, 200× magnification. C, Verhoeff's van Geison staining, 100× magnification. D, Verhoeff's van Geison staining, 200× magnification. B and D, Higher magnification of A and C, respectively.



**Fig. 5.** Cumulative incidence of capsular contracture.

radiotherapy) did not significantly increase the odds of developing capsular contracture (Table 2). Patients who had irradiation only had an approximately 22 times increased odds of developing contracture. Patients who had

capsular contracture were treated with corrective surgery that included capsulotomy and implant exchange. One patient who had preoperative radiotherapy required the addition of a latissimus flap. All patients, including those who had corrective surgery for capsular contracture, had successful outcomes (Fig. 6).

## DISCUSSION

AlloDerm RTU is derived from donated human skin and is processed in a similar manner to AlloDerm RTM. The core tissue processing is identical for both matrices up until the last few steps. AlloDerm RTM is stored in cryoprotective solution and freeze dried<sup>25</sup> while AlloDerm RTU is stored in preservation solution (phosphate buffered solution) and terminally sterilized by electron beam radiation.<sup>26</sup> Before use, AlloDerm RTM requires a rehydration step that may take up to 40 minutes depending on the thickness of the matrix, but usually 20 minutes for most

**Table 2. Univariate Analysis of Chemotherapy/ Radiotherapy as Risk Factors for the Development of Capsular Contracture**

| Risk Factor                      | Capsular Contracture Events (%) | OR (95% CI)        | P             |
|----------------------------------|---------------------------------|--------------------|---------------|
| Radiotherapy only                |                                 |                    |               |
| Yes                              | 50.0                            | 21.8 (1.18–401.46) | <b>0.038*</b> |
| No                               | 4.4                             |                    |               |
| Chemotherapy only†               |                                 |                    |               |
| Yes                              | 9.1                             | 2.7 (0.51–13.95)   | 0.245         |
| No                               | 3.6                             |                    |               |
| Radiotherapy + chemotherapy†     |                                 |                    |               |
| Yes                              | 11.1                            | 2.9 (0.50–17.39)   | 0.235         |
| No                               | 4.1                             |                    |               |
| No radiotherapy or chemotherapy† |                                 |                    |               |
| Yes                              | 0                               | NE                 | NE            |
| No                               | 11.3                            |                    |               |

\*Statistically significant at  $P < 0.05$ .

†Computed at the breast level.

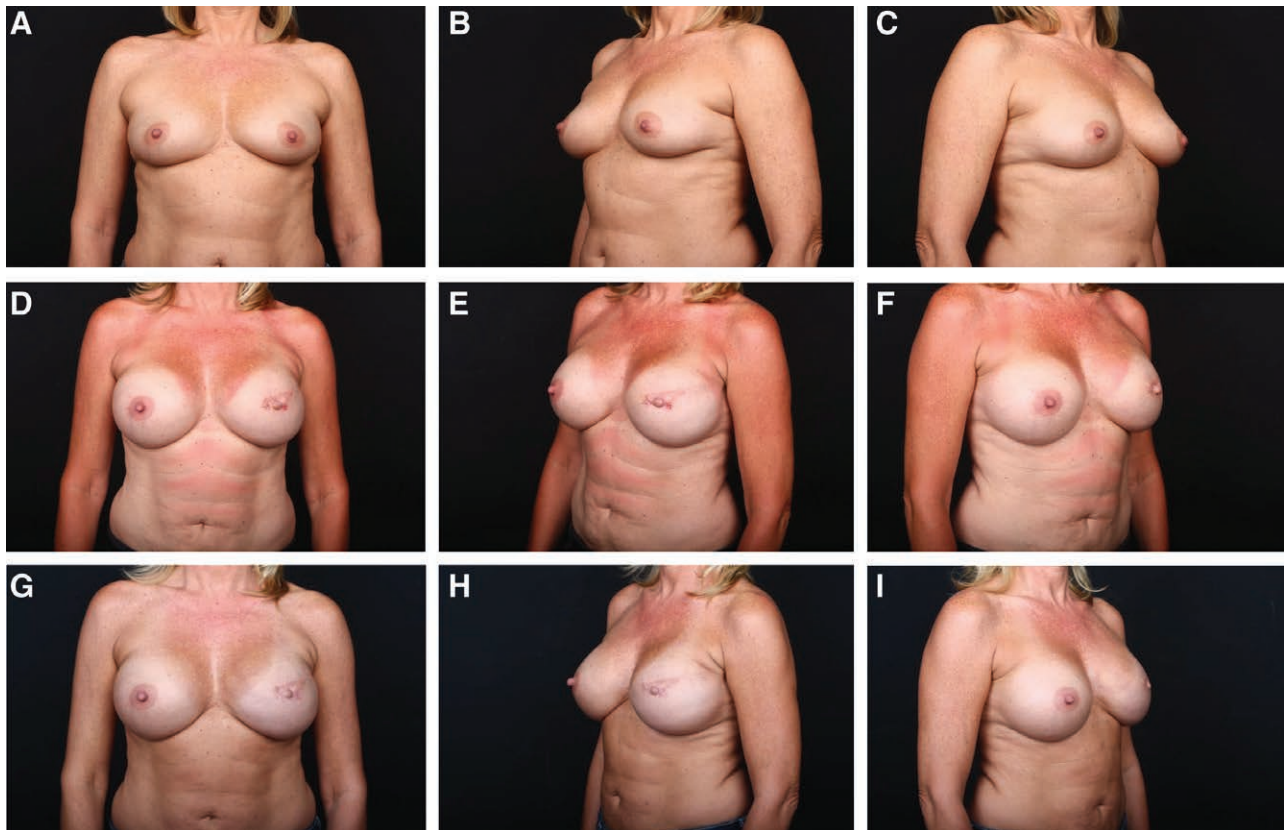
NE, nonestimable.

breast surgery purposes. AlloDerm RTU does not require rehydration as it is supplied rehydrated but a minimal soak time of 2 minutes before use is recommended to remove preservatives.

As the core tissue-processing step is identical to both matrices, implanted AlloDerm RTU is expected to

vascularize, cellularize, and integrate into host tissue in a similar manner to AlloDerm RTM. Although an unpublished primate study demonstrated similar integration of the 2 matrices,<sup>27</sup> there are no published data on AlloDerm RTU integration in the clinical setting.

In this series of 68 patients, we demonstrate that AlloDerm RTU placed at the lower pole during stage 1 reconstruction fully integrates within the host tissue by the time of expander/implant exchange. Integration was confirmed histologically by the presence of neovascularization and cellular repopulation within the graft, which is consistent with tissue viability. Moreover, the mild-to-moderate capillary and fibroblast density and the collagen orientation within the grafts are consistent with those seen in native human skin.<sup>28</sup> It is of importance to highlight here that a common misconception among reconstructive surgeons is that a fully integrated graft should demonstrate robust or significant vessel and fibroblast density. In actuality, a healthy fully integrated graft should have mild-to-moderate vessel and fibroblast density. Significant vessel and fibroblast density is, in fact, a sign of chronic inflammatory response.<sup>29</sup> Fully integrated AlloDerm RTU in our series did not show evidence of chronic inflammatory response, which is consistent with the presence of mild-to-moderate vessel and fibroblast density. In addition, the absence of synovia-like metaplasia within the integrated graft along the graft/cap-



**Fig. 6.** A 50-year-old who underwent left mastectomy followed by immediate AlloDerm RTU-assisted expander/implant reconstruction and right augmentation with round silicone implants (style 45, 650 cc on left and style 20 400 cc on right) and fat grafting × 1. (A-C) Pre-operative, (D-F) 1-year postoperative, and (G-I) 3-year postoperative views.



**Table 3. Complications with AlloDerm RTU Versus AlloDerm RTM**

| Complications            | RTU<br>(N = 116),<br>n (%) | RTM<br>(N = 157),<br>n (%) | P     |
|--------------------------|----------------------------|----------------------------|-------|
| Skin necrosis            | 12 (10.3)                  | 19 (12.2)                  | 0.70  |
| Major                    | 6 (5.2)                    | 10 (6.4)                   | 0.80  |
| Intermediate             | 6 (5.2)                    | 7 (4.5)                    | 0.78  |
| Minor                    | 0 (0)                      | 2 (1.3)                    | 0.51  |
| Seroma                   | 5 (4.3)                    | 12 (7.6)                   | 0.32  |
| Infection                | 3 (2.6)                    | 12 (7.6)                   | 0.105 |
| Exposure/loss of implant | 0 (0)                      | 8 (5.1)                    | 0.02  |
| Capsular contracture     | 6 (5.2)                    | 7 (4.5)                    | 0.78  |

Data for AlloDerm RTM were derived from the authors' previous experience with this matrix. *P* values were computed using Fisher's exact test.

sule interface further supports the absence of chronic inflammation. Synovia-like metaplasia is characteristic of a foreign body response and is a feature of breast implant capsular tissue.<sup>30</sup>

We also demonstrate in this series that AlloDerm RTU can be safely used for breast reconstruction. Rates of skin necrosis, seroma, and infection are similar to those observed in our previous experience with AlloDerm RTM (Table 3). The low rate of infection with AlloDerm RTU in our series is of particular significance, given that a reason for the development of the sterile matrix was to mitigate the risk of infectious complications reported with its non-sterile counterpart.<sup>10–13</sup> A recent study by Zenn and Salzberg<sup>18</sup> also attests to the low infection rate (0.8%) with this matrix. Other published series on AlloDerm RTU, however, have reported higher infection rates, ranging from 6.0% to 25.0%.<sup>15–17,19,20</sup> Although it is difficult to comment on the disparity in infection rates between studies, we believe that strict adherence to aseptic techniques is critical to minimize the risk, even when using a sterile graft.

Clinically significant capsular contracture was the only long-term complication in our series, in 6 breasts (6 patients). The contracture rate of 5.2% with AlloDerm RTU is similar to our previous experience with AlloDerm RTM (4.5%; Table 3) and within the range (0–10%) reported for AlloDerm RTM in the published literature.<sup>6,9,23,31</sup> At the time of expander/implant exchange, there was no indication that these 6 breasts would develop contracture. There was no evidence of fibrosis or foreign body response histologically and by gross observation. Although univariate analysis found significant association between radiotherapy only and the development of capsular contracture, the impact of chemotherapy cannot be excluded, given the low incidence of contracture in this study. The absence of comorbidities (obesity, diabetes, and hypertension) in these patients precluded the evaluation of these variables as potential risk factors for the development of contracture.

This study is limited by the retrospective study design and the absence of an AlloDerm RTM internal control group, although a historic AlloDerm RTM cohort was used to compare postoperative complications. Notwithstanding these limitations, this study provides the first clinical evidence of AlloDerm RTU graft integration and incorporation within the host tissue following breast reconstructive surgery.

## CONCLUSIONS

AlloDerm RTU used in breast reconstructive surgery fully integrates and incorporates into host tissue. There were no unexpected safety concerns with its use, both at short and long term, at least up to 5 years of follow-up.

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