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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

V.L.M. Rundell [a], R.T. Beck [a], C.E. Wang [b,c], K.A. Gutowski [d], M. Sisco [a], G. Fenner [a], M.A. Howard [a,*]

[a] *Division of Plastic Surgery, NorthShore University HealthSystem, Evanston, IL, USA*
[b] *Department of Surgery, NorthShore University HealthSystem, Evanston, IL, USA*
[c] *The Center for Clinical Research Informatics, NorthShore University HealthSystem, Evanston, IL, USA*
[d] *Department of Plastic Surgery, Ohio State University School of Medicine, Columbus, OH, USA*

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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 is 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.

* Corresponding author. NorthShore University HealthSystem, Division of Plastic Surgery, 501 Skokie Blvd, Northbrook, IL 60062, USA. Tel.: +1 (847) 504 2300.
E-mail address: mhoward@northshore.org (M.A. Howard).

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Introduction

The percentage of mastectomy patients who receive a prosthetic breast reconstruction is between 15 and 30%.[1,2] Implant-based reconstruction remains the most common reconstructive technique.[3] 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,[4,5] 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.[6]

A major concern regarding ADM use in breast reconstruction is the potential for increased complications. Single institution reports provide conflicting information[7–9] and recent meta-analyses[10–13] 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[7,14] [See also, Table 1]. Several dermal matrix products are available[15–21] and questions exist as to the impact of differing product manufacturing techniques upon the product performance and patient outcomes.[22] The most studied ADM is AlloDerm (LifeCell Corp, Branchburg, NJ), an aseptically produced dermal matrix product, other ADM products have been less well studied.[15–22]

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.[22] 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[5,6] 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-