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Outcome of the use of acellular-dermal matrix to assist implant-based breast reconstruction in a single centre

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Abstract

Introduction: The use of acellular dermal matrix (ADM) has transformed the technique of implant-based breast reconstruction. It offers the option of a one-stage procedure and is felt to have benefits in cosmetic outcome but the medium and long-term outcomes are unknown.
Methods: All cases where ADM was used in a breast reconstructive procedure in the Edinburgh Breast Unit from its initial use on 7/7/2008 to 31/7/2012 were reviewed retrospectively. Follow up was completed to 30/11/2012.
Results: 147 patients received 232 sheets of ADM (156 Strattice, 73 Permacol and 3 Alloderm). Mean follow up was 687 days. In 40 cases unplanned implant explantation occurred (17.2% or 27.2% of patients). 7 of 27 (25.9%) patients requiring adjuvant therapy had this delayed due to problems with the reconstruction. 30 of 80 patients (37.5%) undergoing unilateral surgery have undergone contralateral surgery. Implant loss varied significantly with smoking (34.6% loss rate in smokers vs 13.2% in non-smokers, $p = 0.001$), with radiotherapy (28.1% loss rate vs 13.8% with no radiotherapy, $p = 0.001$) and with incision type. There was no statistically significant variation by operating surgeon, type of ADM used, chemotherapy use, patient weight, breast weight or nipple preservation. Patients underwent a mean of 1.54 further operations (range 0–7).
Conclusions: While offering potential cosmetic and financial benefits, the use of ADM with implant-based reconstructions has a significant rate of implant loss, further surgery and potential delay in adjuvant therapy. These must be considered when planning treatment and consenting patients.

Keywords: Breast; Mastectomy; Breast reconstruction; Acellular dermal matrix; Surgical complications

Introduction

Implant-based breast reconstruction has tended to be less preferred to myocutaneous flaps because of limitations in cosmetic outcome, requirement for tissue expansion or a two-stage procedure and the need for ongoing maintenance. However, it offers advantages in terms of length of time taken for surgery and recovery, less interference with muscle function and avoids scars elsewhere on the body. The use of acellular dermal matrix (ADM) to augment implant-based reconstruction has in recent years provided the opportunity for a single-stage procedure without tissue-expansion and with suggestions of improved cosmetic outcome compared with submuscular placement, in part due to better inframammary fold definition.[1–3] Despite significant expense for the ADM, cost-savings have been suggested when compared with flap reconstructions due to reductions in theatre time and hospital stay.[4] A variety of materials have been used and include tissue derived from human, porcine and bovine sources, processed in varying manners to produce an acellular, non-reactive, connective tissue support to cover pole of the breast implant. The ADM provides a framework into which the host tissue can integrate. However, there remains very little published evidence of the outcome of this

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technique. Reports of inflammatory reactions to the implanted material and increased failure rates have raised concerns.[5–7]

This paper presents the experience of the Edinburgh Breast Unit using ADM as part of breast reconstruction between the introduction of the technique in 2008–2012. The primary aim of the study was to determine the failure rate of the technique. Secondary objectives were to identify potential risk factors for failure of reconstruction and the implications of this.

Methods

Patients in whom ADM was used were identified from records of material ordered with cross reference to theatre lists. All cases undertaken from the first use of the technique on 7/7/2008 to 31/7/2012 were identified. Retrospective casenote review was performed to provide a dataset for patients with follow up to 30/11/2012. Cases were performed by consultant breast and plastic surgeons with experience in implant-based reconstruction or by more newly appointed consultants with experience of ADM use during training. 10 surgeons performed the primary breast and reconstructive surgery. At least initially, many cases were performed by two consultant breast surgeons or a consultant breast surgeon and a consultant plastic surgeon operating together. Decisions regarding the placement of a definitive implant (as a one-stage procedure) or tissue expander (as a one or two-stage procedure) were made by the individual surgeon with no unit protocol. Drains were placed in all cases. These were removed when drainage was less than 50 mls/per day or at around 7 days. Prophylactic antibiotics were given until drains were removed. No formal assessment of cosmetic outcome was made. The recording of seroma volume and drainage was inconsistent and is therefore not presented. The occurrence of erythema in the first weeks following surgery was not formally reported but is presented where it has been noted. Adjuvant treatment was judged to have been delayed if planned treatment dates were delayed due to complications of surgery. Axillary sampling procedures included those undergoing sentinel node biopsy (61 patients) and those undergoing 4-node sampling (24 patients). Data are presented as mean (range) with median in addition for categories lacking normal distribution. Hazard ratios are presented with 95% confidence intervals. Statistical analysis was performed using univariate and multivariate Cox regression. Only those variables with a univariate p value of less than or equal to 0.2 were included in the model for multivariate analysis. Breast weight was not normally distributed and was log10 transformed prior to analysis in relation to risk of implant loss.

Results

147 patients underwent breast reconstructive surgery using ADM in 222 breasts. Mastectomies were performed to reduce risk ($n = 97$, 43.7%), for primary cancer ($n = 84$, 37.8%), ductal carcinoma in situ ($n = 29$, 13.1%) and cancer recurrence ($n = 12$, 5.4%). 3 patients have had distant cancer recurrence (one died), one patient developed breast recurrence and one an axillary recurrence. Patients had a mean age of 47.4 (range 20–75). Patients had a mean weight of 67.8 kg (43–102) and BMI of 25.3 (16–43). Breast weight, reconstructed breast weight and change in breast weight are presented in Table 1.

71 patients underwent bilateral reconstructions using ADM and 80 had unilateral procedures including 4 who had bilateral surgery using ADM at different times. 30 of the 80 (37.5%) patients having unilateral breast reconstruction underwent contralateral surgery, largely to improve symmetry. 232 sheets of ADM were used in total (156 Strattice (LifeCell, Bridgewater, NJ, USA), 73 Permacol (Covidien, Mansfield MA, USA) and 3 Alloderm (LifeCell, Bridgewater, NJ, USA)). In one case a sheet of Alloderm was too small to achieve implant coverage and a sheet of Strattice was used in addition. In 9 cases patients received further sheets of ADM during revisional surgery.

Mean follow up was 687 days (86–1583). This included 5 patients without complete follow up to 30/11/2012. One had died and 4 were discharged to distant home breast services.

Unplanned implant explantation occurred 40 reconstructions (17.2% of reconstructions involving 27.2% of patients). Implant expantation rate was 9.5% at 3 months and 15.5% at 1 year. Expantations occurred due to wound problems except in two instances of removal of an intact reconstruction on the contralateral side following failure on one side at the request of the patient and another patient where intact bilateral reconstructions were felt to be inadequate and were revised to latissimus dorsi flaps. Median time to loss of implant was 73 days (9–895). 26 reconstructed breasts were recorded as having erythema over the reconstruction in the first 4 weeks following surgery. 70 reconstructed breasts (31.5%) had problems with wound healing. 7 of 27 (25.9%) patients had a delay in adjuvant therapy as a result of problems with the reconstruction. Patients underwent 227 further operations following primary surgery with ADM (mean 1.54 per patient (range 0–7)). This included 55 planned second procedures, largely revision of tissue expander to implant and nipple reconstruction. Mean time to first further operation was 249 days (0–864) with a median of 208 days. 2 patients developed haematomas requiring evacuation following primary

Table 1
Weight of breast at mastectomy, weight of implant/expander used at reconstruction and change in breast weight for 147 patients undergoing 222 mastectomies with implant reconstruction with acellular dermal matrix.

	Mean	Range	Median
Breast weight	509 g	85–2360 g	400 g
Reconstruction weight	406 g	135–765 g	400 g
Change in breast weight	−100 g	−1795 to +550 g	−10 g