**Trends in Post-Mastectomy Breast Reconstruction Types at a Breast Cancer Tertiary Referral Centre Before and After Introduction of Acellular Dermal Matrices**

**Authors**

1Hadyn K.N. Kankam BA Hons. (Cantab.)

1George J.M. Hourston BA Hons. (Cantab.)

2Laura J. Fopp BSc

3, 4John R. Benson MA DM(Oxon) MD(Cantab) FRCS(Eng) FRCS(Ed)

2, 3Sarah L. Benyon BSc MBBS MRCS(Eng) FRCS(Plast)

2, 3Michael S. Irwin MBBS FRCS(Plast)

3Amit Agrawal MBBS MS DM FRCS(Edin)

3Parto Forouhi MSc MB ChB MD FRCS(Eng)

2, 3, 4Charles M. Malata BSc (HB), MB ChB, MRCS LRCP, FRCS(Glasg), FRCS(Plast)

**Affiliations**

1. Cambridge University Medical School, Cambridge, UK
2. Department of Plastic & Reconstructive Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
3. Cambridge Breast Unit, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
4. PostgraduateMedical Institute, Faculty of Health Sciences, Anglia Ruskin University, Cambridge & Chelmsford, UK

**Correspondence to:**

Professor Charles M. Malata, Consultant Plastic Surgeon

Box 186, Department of Plastic and Reconstructive Surgery

Addenbrooke’s Hospital, Cambridge University Hospitals NHS Foundation Trust

Cambridge, United Kingdom

CB2 0QQ

Email: [cmalata@hotmail.com](mailto:cmalata@hotmail.com)

Tel: 01223586672

Fax: 01223257177

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**SUMMARY**

**Background**

Reconstructive breast surgery has continued to evolve over the last decade with a key change being adoption of acellular dermal matrices (ADMs) as an adjunct for implant-based procedures. This retrospective observational study assesses the impact of ADMs on post-mastectomy reconstructive practice performed in a single institution.

**Methods**

We conducted a review of allpatients undergoing breast reconstruction at a University Teaching Hospital for an 18-month period before and after adopting ADMs). Demographic, procedural and complication data for these two cohorts were compared (***χ*2** and Student’s t-tests).

**Results**

A total of 264 women (336 breasts), mean age 47.5 years, were identified; 137 before and 127 after the introduction of ADM. Implant-only reconstructions increased from 16% to 52% following the adoption of ADM (p<0.01), whereas the proportion of both latissimus dorsi (LD) and deep inferior epigastric perforator (DIEP) flap reconstructions decreased significantly (31% to 11%, and 49% to 34% respectively, p<0.01). The rate of early complications for the implant-only procedures was not significantly different with or without ADM (26% versus 20% respectively, p=0.44), despite there being no difference in the rate of adjuvant radiotherapy (22% versus 35% respectively, p=0.30).

**Conclusions**

This study showed that since ADM introduction to our centre, more breast reconstructions have been of the implant-only type with consequent reductions in the more complex and expensive autologous techniques. Implant-only procedures that incorporated ADM use had similar complication rates to those that did not.

**KEYWORDS**

Immediate Breast Reconstruction; Acellular Dermal Matrix; Trends; Outcomes

**INTRODUCTION**

Reconstructive breast surgery has evolved in the UK over the last decade with an increase in rates of immediate breast reconstruction (IBR) (1,2) and introduction of acellular dermal matrices (ADMs) (3). ADMs are animal-derived soft-tissue substitutes that have been decellularized to eliminate an antigenic response or rejection (4). The three main types are obtained from human, pig or calf skin. Their use was first described in reconstructive breast surgery in 2001 but previous applications included treatment of burns and abdominal wall repair, amongst others (5–9). The advantages of ADMs have resulted in widespread adoption and increased use in implant-based breast reconstructive procedures. Potential advantages of incorporating ADMs into subpectoral implant-based reconstruction include: enhanced coverage of the implant inferolaterally, especially in patients with attenuated soft tissues (10, 11); greater initial expander fill volumes, thus enabling reconstruction of larger breasts and single-stage surgery (12); improved definition of the inframammary fold (10,11); and a theoretical reduction in the incidence of radiotherapy-induced capsular contracture (13–15).

ADMs were first introduced to the Cambridge Breast Unit in October 2013. It was surmised that adoption of ADMs had resulted in a significant alteration in patterns of reconstructive workload, with an increased proportion of implant-only reconstructions. With this in mind and reported national trends (1), we decided to review our practice to ascertain whether any changes paralleled findings from other centres around the UK. This study assesses the temporal and practice-changing impact of ADMs on types of post-mastectomy reconstruction performed at a tertiary university hospital comprising three breast surgeons and three dedicated reconstructive plastic surgeons. A secondary objective was to assess clinical outcomes of ADM-assisted reconstruction a new in terms of early complication rates.

**METHODS**

A retrospective review of case notes of patients undergoing immediate or delayed post-mastectomy breast reconstruction at a university hospital for a period of 18 months before and after adoption of ADMs was conducted. The study period was between April 2012 and April 2015 in order to allow for a minimum follow up of one year. Patients were identified from reconstruction diaries and operating theatre registers. For these two patient cohorts, demographic, procedural, and post-operative data were collected. The latter included details of any failed implant-only reconstructions and plans for adjuvant radiotherapy. Implant removal within 3 months of surgery constituted a reconstruction failure and this time frame excluded radiotherapy-induced complications occurring beyond 3 months. Routine expander to implant exchange was not considered to be a failure when carried out as a planned procedure and longer term effects of radiotherapy on breast reconstruction was not the subject of the present study.

Complications occurring within 12 months of surgery were recorded for all implant-only breast reconstructions, irrespective of ADM usage. Complications recorded were infection, wound dehiscence, seroma formation, haematomas requiring evacuation and Baker grade III or IV capsular contracture. A high clinical index of suspicion for infection with wound exudate, pyrexia or erythema was confirmed with swab cultures and C-reactive protein (CRP) levels.

**Surgical technique – implant and ADM reconstructions**

All mastectomies were performed by a breast surgeon with subsequent reconstruction by a plastic surgeon. For implant-only procedures that incorporated the use of ADMs, the sub-pectoral pocket was dissected with release of the inferomedial border of the pectoralis major. After washing in aqueous betadine solution, implants were placed in the sub-pectoral pocket. ADMs were prepared by rehydration and positioned along the inframammary fold with suturing to the inferolateral free border of the pectoralis major above and chest wall below. An illustrative video provides the salient surgical details (16).

**Statistical analysis**

Baseline characteristics and pre- and post-operative data were compared between the pre- and post-ADM cohorts using chi-squared tests for categorical variables. Continuous variables such as patient age were compared using Student’s t-test. Complication, failed implant-only reconstruction and adjuvant radiotherapy rates were compared in implant-only procedures with and without an ADM using chi-squared tests.

This study was reported using the STROBE checklist as a framework (17).

**RESULTS**

A total of 264 reconstruction patients (336 breasts) with a mean age of 47.5 years were identified over the three-year period of the study; 137 (166 breasts) were operated on before and 127 (170 breasts) after introduction of ADMs. The mean age was 47.5 years and did not differ significantly between the two cohorts (p=0.265) [**Table 1**].Interestingly, mastectomy rates fell significantly during the time period of this study from 39% before to 33% after ADM introduction (p=0.028). The indications for mastectomy are summarised in **Table 1**. A significant reduction in the number of mastectomies performed for unilateral breast cancer was seen following the adoption of ADMs (76% to 61%, p=0.009). These coincidental changes accounted for the relatively low number of reconstructions performed over the three-year period.

There was a significant change in the types of breast reconstruction performed after introduction of ADMs compared to a similar period before this. This consisted of a large increase in use of implant-only techniques (16% to 52%, p<0.001); and a concomitant decrease in latissimus dorsi (LD) flap and deep inferior epigastric perforator (DIEP) flap reconstructions (31% to 11%, p<0.001; and 49% to 34%, p=0.003, respectively) [**Table 2**]. Other abdominal wall flap reconstruction types did not change significantly, although a decrease in numbers of both TRAM and SIEA flap reconstructions was observed (p=0.729). When analysing the data by number of patients rather than number of breasts, the trend was similar, with significant changes for both implant-only and LD flap procedures [**Table 1**]. A similar pattern was observed in immediate breast reconstruction (IBRs) [**Table 3**]. Interestingly, these trends in breast reconstruction type were broadly similar for each of the three plastic surgeons active within the study. [**Tables 4, 5, and 6**].

A summary of breast surgical procedures performed throughout the study period is displayed in **Table 2**. The proportion of breast surgery procedures did not vary significantly following introduction of ADMs. However, the number of cases of nipple-sparing mastectomy increased from 2 before to 13 after introduction of ADMs (p=0.004). The proportion of patients undergoing surgery on the contralateral breast increased significantly from 22% to 39% (p=0.003) [**Table 1**]. The percentage of patients who received axillary surgery did not change significantly (p=0.208) [**Table 1**]. Moreover, the proportion of therapeutic mastectomies receiving chest wall irradiation did not change significantly between cohorts (47% pre-ADM and 45% post-ADM, p=0.805) [**Table 2**].

The majority (98%) of implant-only procedures were single-stage, using either permanent expandable or fixed-volume implants. The type of implant used for implant-only reconstructions did not change significantly following the introduction of ADMs, with a similar range of temporary expanders, expandable implants, and fixed volume implants (0% to 4.5%, p=0.271; 92% to 87%, p=0.427; and 7.7% to 9.0%, p=0.836, respectively).

Overall, complication rates for implant-only procedures did not differ significantly according to whether ADM was used or not (20% without ADM versus 26% with ADM, p=0.440) [**Table 7**]. Additionally, the failure rate among implant-only reconstructions performed during the study period remained low (p=0.412). Furthermore, the proportion of patients undergoing implant-only reconstruction without ADMs in receipt of post-mastectomy radiotherapy did not differ significantly from those patients with ADMs (35% versus 22% respectively, p=0.301). Amongst the implant-only procedures performed in the three-year study period, there were 65 breasts incorporating ADMs ( 20 StratticeTM (31%), and 45 SurgiMend® (69%)).

**DISCUSSION**

This single centre study has confirmed an increase in implant-only breast reconstruction since introduction of ADMs. This has been accompanied by a corresponding reduction of more complex autologous flap-based techniques. Implant-only procedures now represent half of all breast reconstruction procedures performed in our institution compared to a mere 16% before the advent of ADMs. Latissimus dorsi (LD) flap reconstructions have dramatically decreased from approximately one third to one tenth and deep inferior epigastric perforator (DIEP) flaps from approximately half to one-third of all reconstructions. These trends are observed for both patient-based and breast-based analyses suggesting that patients undergoing bilateral reconstruction are more likely to opt for the same procedure on both breasts.

The perception of the surgeons was that implant-only reconstructions increased in number after ADM introduction because they were offered to some patients with planned postoperative radiotherapy as they were undergoing a procedure that incorporated ADMs. Interestingly, contrary to these expectations, the proportion of implant-only reconstruction patients receiving adjuvant radiotherapy has not changed significantly. There are potential protective effects of ADMs against radiation-induced capsular contracture, but there is no evidence that surgeons were preferentially offering reconstruction with implant and ADM to those patients in whom post-mastectomy radiotherapy was anticipated (13–15).

Policy changes aimed at reducing historically high re-excision and mastectomy rates were introduced in 2013 and broadened the indications for breast conserving surgery. These led to a reduction in numbers of mastectomies for unilateral breast cancers coincidental with ADM introduction.

The use of ADM in post-mastectomy reconstruction has not resulted in increased complication rates which have been reported by some groups (18,19).

When ADMs were first available , porcine-derived Strattice TM matrix was initially used in our institution (Acelity, San Antonio, TX, USA) but the calf-derived SurgiMend®(TEI Biosciences Inc, Boston, MA, USA) has been utilised exclusively for the past 3 years (since May 2014). To evaluate these ADMs in terms of safety and efficacy, a randomised trial comparing these two ADMs in the setting of immediate reconstruction is being conducted in Denmark (trial not yet published; ClinicalTrials.gov Identifier: NCT02521623). The authors have also undertaken a recent study comparing SurgiMend® with StratticeTM (16,20).

The present study is limited by relatively small numbers of patients and a short follow up period. Nonetheless, this patient cohort represents a workload equivalent to 30 reconstructions per surgeon per year and we have been able to follow up patients included within the study all of whom have complete data collection for monitoring of early complication rates.

National trends in post-mastectomy immediate breast reconstruction (IBR) within the UK have recently been evaluated (1). The proportion of immediate implant-only reconstructions performed in the Cambridge Breast Unit is comparable to figures for the UK as a whole. However, the use of implant-only based reconstructions has been falling at a national level (despite remaining the commonest type of reconstruction), but the current study reveals an opposite trend with a surge in use of implant only and a sharp decline in autologous flap based reconstruction. This is most evident for LD flaps whilst DIEP flaps remain the pre-eminent autologous tissue technique (at 71% of all the autologous reconstructions and one third of all reconstructions). These findings for LD flap-based immediate breast reconstruction are in agreement with the study of Leff and colleagues examining local and national trends in immediate post-mastectomy breast reconstruction between 2004 and 2013 (which thus precedes the period of our study (2013 – 2015)). A curve fitting analysis confirmed a proportional decline in LD flap procedures between 2008 (n= 1378)and 2012 (n= 1090). Of note, this study found implant-based immediate breast reconstruction remains the most common procedure but reported an increase in non-LD autologous free flap procedures which contrasts with the current study.

The results of the present study are more closely aligned with the observations made by several investigators in the USA, which include a rise in implant-based and decline in autologous reconstructions(21,22). In the USA, where the reconstructions are predominantly performed by plastic surgeons, ADMs have been incorporated into over 60% of all implant-based reconstructions (5) which is almost identical to the 57% herein reported in Cambridge.

The trends observed in our centre and across the USA; an increasing popularity of implant-only reconstructions over autologous tissue techniques, may be partially explained by the adoption of ADMs. This interpretation is most suited to our data. However, a contributing factor to LD flap reconstructions falling out of favour, as suggested by Leff *et al* may be the postoperative complications associated with this technique (1). These include seroma formation (23), breast animation (24) and functional shoulder weakness (25). ADMs provide similar cover for the implant to that provided by the LD muscle but without sacrificing any muscle and avoiding a donor scar. Therefore implant-only reconstruction with ADM may contribute to improved global-health related quality-of-life which could increase demand for this type of reconstruction. Additionally, implant-only reconstruction appears cheaper in the short term and this could partly explain an increase in popularity amongst surgeons and healthcare providers especially within a publically-funded national health service.

It should be noted however that ADMs can be associated with complications such as seromas or red breast syndrome as well as a higher chance of implant ruptures/removal, and revisional surgery (including conversion to autologous tissue reconstruction in the long run (26)). When future cost-benefit analyses for ADMs are carried out these clinical together with patient-reported outcome measures need to be closely monitored.

**CONCLUSION**

The present study showed that since ADM introduction to our centre, more breast reconstructions have been of the implant-only type with consequent reductions in the more expensive autologous tissue techniques (27,28). ADM use in post-mastectomy reconstruction has not resulted in increased complications contrary to widespread reports (18,19). The possibility of post-operative radiotherapy was not seen as a total contraindication for implant-only reconstruction even though the numbers undertaken for this reason don’t seem to have increased as thought by the reconstructive surgeons. We aim to prospectively monitor the long-term outcomes including revision rates and whether they justify the increased initial cost of the implant-only reconstructions.

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**TABLES**

**Table 1.** Clinical data of breast reconstructions performed before and after ADM introduction (by patient)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pre-ADM | Post-ADM | p value (*χ*2 test) |
| Patients (n) | 137 | 127 | - |
| Age (years) | 48.1 | 46.8 | 0.265 (Student’s t-test) |
| Contralateral breast surgery (%) | 21.9 | 38.6 | 0.003\* |
| Axillary surgery (%) | 80.9  *(n=93/115)* a | 73.9  *(n=82/111)* b | 0.208 |
| Indication for mastectomy (%) c  Unilateral cancer  Unilateral prophylaxis  Unilateral salvage  Bilateral cancer  Bilateral prophylaxis  Ipsilateral cancer and contralateral prophylaxis  Bilateral salvage  Burn | 76.1  0  3.7  0.7  7.5  11.9  0  0 | 61.1  1.6  2.4  5.6  11.9  15.1  1.6  0.8 | 0.009\*  0.143  0.529  0.025  0.225  0.459  0.143  0.301 |
| Type of reconstruction (%)  Implant-only  LD flap  DIEP flap  Other abdominal wall flaps | 12.4  32.8  50.4  4.4 | 43.3  14.2  39.4  3.1 | <0.001\*  <0.001\*  0.073  0.601 |

1. Axillary surgery data unavailable for 22 patients
2. Axillary surgery data unavailable for 16 patients
3. Indication data unavailable for 4 patients

**Table 2.** Clinical data of breast reconstructions performed before and after ADM introduction (by breast)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pre-ADM | Post-ADM | p value (*χ*2 test) |
| Breasts (n) | 166 | 170 | - |
| Breast surgery procedure (%)  Skin-sparing mastectomy  Nipple-sparing mastectomy  Le-Jour pattern mastectomy  Wise pattern mastectomy  Toilet mastectomy  Capsulectomy & implant removal  Delayed reconstruction | 75.3  1.2  4.2  1.2  0  3.6  14.5 | 72.9  7.6  1.8  3.5  0.6  4.1  9.4 | 0.621  0.004\*  0.186  0.162  0.322  0.811  0.153 |
| Type of reconstruction (%)  Implant-only  LD flap  DIEP flap  Other abdominal wall flaps | 15.7  31.3  49.4  3.6 | 52.3  11.2  33.5  2.9 | <0.001\*  <0.001\*  0.003\*  0.729 |
| Radiotherapy – planned (%) | 46.7  *(n=56/120)* b | 45.0  *(n=50/111)* c | 0.805 |

1. Indication data unavailable for 4 breasts
2. 120 breasts were treated for cancer
3. 111 breasts were treated for cancer

**Table 3.** Distribution of immediate breast reconstructions performed before and after ADM introduction

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pre-ADM | Post-ADM | p value (*χ*2 test) |
| Breasts (n) | 142 | 154 | - |
| Implant-only (%) | 17.6 | 55.9 | <0.001\* |
| LD flap (%) | 32.4 | 9.7 | <0.001\* |
| DIEP flap (%) | 47.2 | 31.2 | 0.005\* |
| Other abdominal wall flaps (%) | 2.8 | 3.2 | 0.830 |

**Table 4.** Surgeon 1 – Types of breast reconstruction performed before and after ADM introduction

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pre-ADM | Post-ADM | p value (*χ*2 test) |
| Breasts (n) | 64 (50 patients) | 74 (54 patients) | - |
| Implant-only (%) | 10.9 | 47.3 | <0.001\* |
| LD flap (%) | 10.9 | 2.7 | 0.051 |
| DIEP flap (%) | 78.1 | 43.2 | <0.001\* |
| Other abdominal wall flaps (%) | 0 | 6.8 | 0.034\* |

**Table 5.** Surgeon 2 – Types of breast reconstruction performed before and after ADM introduction

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pre-ADM | Post-ADM | p value (*χ*2 test) |
| Breasts (n) | 55 (47 patients) | 58 (46 patients) | - |
| Implant-only (%) | 27.3 | 56.9 | 0.001\* |
| LD flap (%) | 38.2 | 19.0 | 0.023\* |
| DIEP flap (%) | 29.1 | 24.1 | 0.551 |
| Other abdominal wall flaps (%) | 5.5 | 0 | 0.071 |

**Table 6.** Surgeon 3 – Types of breast reconstruction performed before and after ADM introduction

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pre-ADM | Post-ADM | p value (*χ*2 test) |
| Breasts (n) | 23 (20 patients) | 34 (24 patients) | - |
| Implant-only (%) | 13.0 | 61.8 | <0.001\* |
| LD flap (%) | 65.2 | 17.6 | <0.001\* |
| DIEP flap (%) | 21.7 | 20.6 | 0.917 |

**Table 7.** Complication rates following implant-only reconstructions with or without ADM use

|  |  |  |  |
| --- | --- | --- | --- |
|  | Without ADM | With ADM | p value (*χ*2 test) |
| Breasts (n) | 50 | 65 | - |
| Capsular contracture (%) | 12.0 | 6.2 | 0.270 |
| Haematoma (%) | 4.0 | 0 | 0.104 |
| Infection (%) | 4.0 | 13.8 | 0.075 |
| Seroma (%) | 2.0 | 6.2 | 0.279 |
| Wound dehiscence (%) | 4.0 | 3.1 | 0.789 |
| Radiotherapy – planned (%) | 35.0  *(n=7/20)* a | 22.2  *(n=8/36)* b | 0.301 |
| Failed reconstruction (%) | 4.0 | 1.5 | 0.412 |

1. 20 breasts were treated for cancer
2. 36 breasts were treated for cancer