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# Single-stage immediate breast reconstruction with acellular dermal matrix: Experience gained and lessons learnt from patient reported outcome measures

A. Apte, M. Walsh*, S. Chandrasekharan, A. Chakravorty **

*Colchester Hospital University NHS Foundation Trust, Colchester General Hospital, Turner Rd, Essex, CO4 5JL, UK*

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## Abstract

*Introduction*: Acellular Dermal Matrix (ADM) assisted breast reconstruction has transformed the single-stage Immediate Breast Reconstruction (IBR) with an impact on the cosmetic outcomes. However, there is limited data available on patient reported outcomes. This study highlights the Patient Reported Outcome Measures (PROMs), post-operative complications and lessons learnt from ADM assisted single-stage immediate breast reconstruction.

*Methods*: This prospective study enrolled consecutive patients from Feb 2012 – May 2015 undergoing mastectomy with direct-to-implant ADM assisted breast reconstruction, using Strattice™ (Acelity, San Antonio, TX, USA). Patients were recruited from the beginning of our unit's use of ADMs and completed a post-operative questionnaire at 6 weeks, covering pre-operative, operative and post-operative outcomes. Information on tumour biology and post-operative complications was obtained from the medical notes.

*Results*: This study included 49 patients undergoing a total of 53 procedures. Following surgery 93.3% of women reported a high level of body confidence when clothed. 6.7% of patients reported severe post-operative pain during the first week. Mean length of hospital stay was 1.7 days, return to light activities was within 2.5 weeks and normal activities in 5.4 weeks. Implant loss at 3 months occurred in 5.7% of procedures, of which two thirds were smokers.

*Conclusions*: PROMs for Strattice™ ADM based reconstruction show high levels of satisfaction with cosmetic outcomes, low incidences of severe post-operative pain and a short recovery process. PROMs help us to better describe patients' experience, allowing women to make more informed choices about ADM based breast reconstruction, which reassures and helps to achieve better outcomes.


*Keywords:* Acellular dermal matrix; Patient reported outcome measures

## Introduction

Breast cancer remains the most common cancer in the UK with a lifetime risk of one in eight women.[1] Every year over 16,000 women in the UK undergo mastectomy, of which a third also have a reconstructive procedure.[2] Breast reconstruction following mastectomy can be either implant-based, autologous or a combination of both procedures. Implant based reconstruction in the UK constitutes 37% of the reconstructions performed following mastectomy, whilst in the US it is up to 83%.[3,4] The American Society of Plastic Surgeons reports that up to half of their implant based reconstructions utilise an acellular dermal matrix (ADM).[5] ADMs are being increasingly used worldwide and are thought to confer a number of benefits. These include creation of a larger implant pocket, improved control of the inframammary fold and reduced capsular contracture rates.[6–10] This facilitates a single stage reconstruction and improved cosmesis compared with a conventional sub-muscular implant

*Abbreviations:* SMR, submuscular reconstruction; ADM, acellular dermal matrix; IBR, immediate breast reconstruction; PROMs, patient reported outcome measures.

* Corresponding author. Tel.: +44 1206 744776.
** Corresponding author. Tel.: +44 1206 744776
*E-mail addresses:* anuapte@gmail.com (A. Apte), maia.walsh@hotmail.com (M. Walsh), Sekharan.Chandra@colchesterhospital.nhs.uk (S. Chandrasekharan), arunmoy.chakravorty@colchesterhospital.nhs.uk (A. Chakravorty).

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based reconstruction (SMR).[9,11–15] The concept of direct-to-implant breast reconstruction using an ADM, was introduced in 2001 by Salzberg and has gradually gained acceptance. Initially reports of higher complication rates with ADMs compared to SMR raised concerns over the technique, however publications in the last 3 years demonstrate decreasing complication rates.[10,11,16–20] The recent decrease in complication rates is likely due to more experience with ADMs, which has helped improve the surgical technique and patient selection.[11,18–20]

Patient satisfaction of both the surgical reconstructive process and the overall outcomes are a key consideration in determining the effectiveness of an approach.[21,22] The aim of this study is twofold, firstly to highlight the patient reported outcome measures (PROMs) of consecutive single stage direct-to-implant based reconstruction using Strattice™ (Acelity, San Antonio, TX, USA) and to share how surgical and PROMs data has informed our clinical practice, enabling us to achieve results comparable to the standards set out in the oncoplastic breast reconstruction guidelines and ABS-BAPRAS guidelines on the use of ADMs.[23,24]

## Methods

This prospective study recruited consecutive patients from February 2012 – May 2015, from the beginning of our unit's use of ADMs. All patients were offered a full range of reconstructive options including conventional SMR and flap based reconstruction. These options were discussed in detail with both a consultant oncoplastic breast surgeon and separately with a breast care nurse and the limited availability of long-term data on the use of Strattice™ was stated clearly. There were no absolute exclusion criteria for ADM based reconstruction. The study enrolled all patients who chose to undergo skin or nipple sparing mastectomy with direct-to-implant ADM assisted breast reconstruction, using Strattice™ (Acelity, San Antonio, TX, USA). Patients were invited to complete a questionnaire 6 weeks after surgery, which covered pre-operative, operative and post-operative outcomes. The pre-operative section included information about smoking, discussion of all the reconstructive options and whether enough information and time was given for decision making. The in-hospital section covered length of hospital stay and pain control. Post-operative information included: duration to get back to light and normal activities, post-operative pain, cosmetic outcome and overall patient satisfaction. Information on tumour biology, adjuvant treatment, analgesia, antibiotic regimens and post-operative complications was obtained from the medical notes. The questionnaire and study design used to evaluate PROMs was approved by the audit department at Colchester Hospital University NHS Foundation Trust in collaboration with the clinical staff and breast care nurses. This PROMs questionnaire is based on a questionnaire used previously in our unit to evaluate outcomes following autologous breast reconstructions.

At the time of induction, patients received IV co-amoxiclav (1.2 g) alone or in combination with gentamicin (2–3 mg/kg). Thereafter 2 doses of IV and 7 days of oral co-amoxiclav (625 mg TDS) were given. In patients allergic to penicillin, IV Teicoplanin (400 mg) and oral clarithromycin (500 mg bd) were used. Cases were performed by two experienced consultant oncoplastic breast surgeons, with one consultant performing 80% of the procedures. Similar surgical techniques, closely supervised follow-up and adherence to protocols were maintained. Anatomically shaped (tear drop), fixed volume breast implants (Memory shape®, Mentor Worldwide LLC, Santa Barbara, CA, USA) were used. Two drains were inserted during the surgery; one underneath the mastectomy flap and the other in the sub-pectoral region close to the implant. The sub-pectoral drain was removed 24–48 hours after surgery, while the second drain was left for 7–10 days depending on the volume of drainage. Pain control was achieved with a combination of intraoperative 2% chirocaine in 100 ml saline injected subcutaneously and post-operatively with patient controlled analgesia for the first 12 hours followed by opiates and simple analgesics.

## Results

This study included 49 patients of whom 4 underwent bilateral procedures resulting in a total of 53 procedures. 47 patients had mastectomies for breast cancer (2 bilateral) and 2 patients had bilateral risk reducing mastectomies. Patient age, tumour biology and additional treatment are shown in Table 1.

### *PROMs*

The questionnaire response rate was 91.8% (45/49) with the following findings. 100% (45/45) of patients received written information about breast reconstruction. The responses to questions related to body confidence are shown

Table 1
Patient demographics, tumour biology and additional treatment.

| | |
|---|---|
| Mean age | 52.5 yrs (SD 11.2 yrs) |
| Type of procedure | |
| Unilateral | 45 |
| Bilateral | 4 |
| Cancer type | |
| Invasive lobular cancer | 7 |
| Invasive ductal cancer | 29 |
| Mixed | 3 |
| Ductal cancer in situ | 10 |
| Receptor status | |
| ER positive | 42 |
| HER-2 positive | 9 |
| Adjuvant treatment | |
| Radiotherapy | 14 |
| Adjuvant chemotherapy | 16 |
| Herceptin | 8 |
| Neo adjuvant chemotherapy | 6 |
| NPI | 3.8 (SD 1.1) |

SD – Standard Deviation.