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## Clinical and patient reported outcomes in breast reconstruction using acellular dermal matrix

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### ARTICLE INFO

*Article history:*

Received 29 April 2018

Accepted 20 June 2018

Available online 5 July 2018

*Keywords:*

ADM

Breast reconstruction

Mastectomy

Breast cancer

### ABSTRACT

*Introduction:* There is a lack of published patient reported outcome measures (PROMs) for the use of acellular dermal matrix (ADM) based breast reconstruction. This cohort study reviewed our clinical outcomes and PROMs.

*Methods:* All patients undergoing mastectomy with ADM assisted immediate breast reconstruction under a single surgeon between June 2013 and June 2017 were included. A prospectively kept database, clinic letters and operation notes were analysed. All patients received BREAST-Q™ pre and post-operative questionnaires.

*Results:* Sixty-two consecutive patients with 77 reconstructions were included. Mean hospital stay was 3.3 days. All patients received 48 h of intravenous antibiotics, followed by a two-week course of oral antibiotics. Mean post-operative follow up was 17 months. There were 8 cases of skin necrosis (10.4%), and 1 infection (1.3%). These resulted in 4 explantations (5.2%); 3 following skin necrosis and 1 following infection. There was no observed 'red skin' syndrome. Post-operative mean score for 'satisfaction with outcome' was 83.1%. Mean score for 'Psychosocial well-being' was 70.7% and the mean score for 'physical well-being' was 77.9%.

*Conclusion:* Our complication rates were comparable to those published, and PROMs were consistently good. The skin necrosis rate was potentially due to earlier practice of performing single-stage immediate reconstruction using fixed volume breast implants. We have modified our patient selection criteria and ADM based

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reconstructive techniques with experience. Longer term clinical and patient reported outcome should be sought.

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## Introduction

Breast cancer represents the commonest malignancy in the UK, with around 55,200 new cases in 2014, accounting for 31% of cancers in women.<sup>1</sup> Mastectomy and immediate reconstruction is now commonplace; just under half of women undergoing surgery for breast cancer have a mastectomy and a third of those undergoing mastectomy have an immediate reconstruction.<sup>2,3</sup>

Options for immediate reconstruction remain varied but implant based reconstruction remains the most popular with 37% of immediate breast reconstructions in the UK being implant based.<sup>3</sup> The use of acellular dermal matrix (ADM) has been gaining popularity for its use in ameliorating some of the aesthetic challenges faced with implant based reconstruction. ADM provides a scaffold upon which the patient's own cells may repopulate and vascularize, allowing breast surgeons a means by which to cover an implant with vascularised soft tissue. In addition, ADM enables better definition of the inframammary fold and a more natural projection and ptosis. Statistics for the use of ADM in the UK are hard to quantify but in America it is used in over half of implant based reconstruction.<sup>4</sup> The literature surrounding ADM in breast reconstruction though becoming more commonplace is still difficult to analyse. Recent reviews have been unable to come to conclusive statements on its safety and benefits owing to a lack of comparable data and the wide variety of products on the market. A review in 2017 found only twelve studies comparing ADM to no ADM, one of which was prospective and randomised but encompassed very small numbers. The same review also found only 10 studies looking at post-operative complications with ADM (no comparator group), only 3 of which were prospective. Of those studies looking at post-operative complications, explantation rates ranged from 0% to 11%. The wide range of published complication rates and limited published high-grade evidence makes it difficult to come to firm recommendations of its use.

Breast surgery is fundamentally deforming and can have negative effects on body image and self-esteem which can result in depression, anxiety, shame and even suicide.<sup>5</sup> Patient's own perceptions of the impact of breast cancer and surgical treatment are increasingly being recognised as fundamental to understanding overall health outcomes.<sup>6,7</sup> It is thus imperative to use external methods of assessment of quality of life in the form of Patient Reported Outcome Measures (PROMs). The BREAST-Q is an independently validated scoring system for collecting patient reported outcome measures and has a specific module for breast reconstruction.<sup>8</sup> The BREAST-Q examines two domains; patient satisfaction and patient quality of life. Under these two domains are six subthemes (Physical, Psychosocial and Sexual well-being under quality of life; Satisfaction with breasts, Satisfaction with overall outcome and Satisfaction with Care under patient satisfaction).<sup>9</sup>

The aims of this study are firstly to examine our own surgical outcomes and secondly to collect PROMs data in order to fully assess our units' quality of care and to add to the growing body of evidence on the use of ADM.

## Method

This prospective cohort study recruited 62 consecutive patients with 77 reconstructions from June 2013 to June 2017. Included were all patients who underwent mastectomy and immediate reconstruction with implant and ADM under a single surgeon. All patients underwent consultation with both an oncoplastic trained surgeon and specialist breast care nurse to discuss the full range of

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