

Acellular dermal matrix (ADM) assisted breast reconstruction procedures

Joint Guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons

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This document has been produced with the involvement of the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons. Recommendations have been derived after a review of published data regarding the use of acellular dermal matrix in breast reconstruction. Each recommendation is assigned a "level of evidence" (I-V) adapted from the designations set by the Centre for Evidence Based Medicine and others (discussed in detail in Appendix A).

1. Background

The use of implant based reconstruction (IBR) accounts for 37% of immediate reconstructions following mastectomy in the UK. However, complication rates associated with this technique can approach 40% and include capsular contracture, rippling of the implant and mechanical shift of the implant [1]. Upto 40% of patients may require further re-operative surgery [2].

The use of acellular dermal matrices (ADM's) in breast reconstructive surgery is well described in the North American literature but is a relatively new technique in the UK. The reported benefits are related to aesthetic outcome (better inframammary fold definition, greater projection, more natural look), a shorter timescale to the final result and reduced cost to the patient and health care economy (potentially one procedure, fewer outpatient visits).

Concerns have been raised however over the rate of complications, which may be related to patient selection, surgeon experience and training. Initial reports indicated higher rates of postoperative infection, skin necrosis and post operative seroma following the use of ADM. However, more recent comparisons have shown that improving surgical technique and perioperative management can result in improved aesthetic outcomes without any difference in complication rate [1].

As for all new techniques, prospective long term follow-up is needed to ascertain benefit and long term safety data. The Association of Breast Surgery and BAPRAS supports the introduction of a National prospective audit/ database for this technique, but in the interim suggests all cases be audited locally.

2. The aims of this document are to:

- i) describe clinical criteria, guidelines, quality criteria and audit for acellular dermal matrices (ADMs) in breast reconstruction procedures for those units introducing this new technique
- ii) inform those developing and commissioning services of the identified clinical standards and quality indicators associated with the procedure
- iii) suggest a standard approach to commissioning and coding these procedures

The source material for the document are published articles in peer review journals. Randomised trial data for breast reconstruction using ADM does not exist and most publications are series from large centres in the USA.

3. Clinical Indications for ADM assisted implant reconstruction:

- i) Planned immediate breast reconstruction procedure following full discussion at the diagnostic MDT
- ii) As a potential alternative to 2 stage reconstruction of breast using expander / implant based reconstruction
- iii) Knowledge and acceptance that the reconstruction involves a breast implant. (*There is no set lifespan of a breast implant, although patients must be aware of the probability for future revision [3])
- iv) Estimated mastectomy weight of <600gms (increased infection rate associated with breast sizes >600gms [4] [level III])
- v) Adequate skin envelope

Relative indications:

- i) Patients who do not wish to undergo a myocutaneous flap procedure (* ADM may replace the latissimus dorsi flap in some patients but experience in the surgical technique is essential. Lower complication rate if expander used instead of implants >500cc [level 5])
- ii) Patients requesting bilateral mastectomy with immediate reconstruction (risk of complications may be higher in bilateral cases).
- iii) Risk reducing surgery

Cautions:

- i) Patient of body mass index >30 have greater risk of complications [5][level II]
- ii) Increased infection rates in patients undergoing simultaneous axillary clearance [level V]
- iii) Patients requiring post-operative chest wall radiotherapy have a four fold increase in postoperative complications [6][level III]. There is an increased risk of capsular contracture post radiotherapy [7][level IV]. ADM does not increase the risk of capsular contracture post radiotherapy and there are emerging data to suggest it may potentially reduce the severity of capsular contracture [7][level IV]. However, there is no definitive data and caution is to be exercised.
- iv) Smoking history. Patients with a history of smoking, or who continue to smoke, have a higher risk of implant failure.[level III]

4. Quality Criteria and Audit:

Concerns have been raised over the increased risk of complications for ADM assisted breast reconstruction procedures. Units wishing to undertake ADM assisted implant reconstruction are required to audit all cases prospectively.

As per the National Mastectomy and Breast Reconstruction Audit (NMBRA) [8], the following 'Quality Criteria' should be audited. For each criteria the NMBRA outcome has been stated, followed by a Target Standard individual Units should aspire to, once experienced in the technique.

i. Surgical techniques are improved to reduce local complications following skin sparing mastectomy

NMBRA outcome: 7.6% of patients returned to theatre for local complications (wound infection or skin flap necrosis requiring debridement, and haematoma)

Target Standard: <5% of patients return to theatre for local complications

ii Post-operative infections are reduced by careful intra-operative technique and peri-operative infection control.

NMBRA outcome: 25% of patients required antibiotics by 3/12 for suspected infection

Target Standard: <10% of patients require antibiotic

iii Implant loss at 3 months is assessed and audited

NMBRA outcome: 9% of immediate breast reconstruction (IBR) and 7% delayed breast reconstruction (DBR) patients reported implant loss

Target Standard: complications leading to implant loss occur in <5% of patients

iv Patient Reported Outcome Measures (PROMS) are used to assess patient experience of information and outcomes

NMBRA outcome: 50% of patients received written information about breast reconstruction

Target Standard: 100% of patients receive written information about breast reconstruction

5. Centres wishing to be commissioned for ADM assisted reconstruction procedures need to demonstrate the following:

Unit Criteria

- Experienced breast reconstructive team
- Prospective record and photographic collection
- Patient written information on ADM technique
- Guidelines to staff on post-operative management with agreed protocols of care (drains, follow-up etc.)
- Demonstrate acceptable results of IBR using standard technique

Organisational Criteria:

- Approval from the New Procedure Policy/Clinical Governance board specific to each Hospital Trust
- Patient awareness they are being offered a relatively new procedure with limited knowledge of outcomes and complications
- Patient acceptance of porcine dermis
- Clear pathway and service arrangement to manage breast drains for upto 3 weeks for follow up care
- Ongoing local review and audit of all complications arising from all breast reconstruction procedures
- Agreement to participate in a national clinical ADM (Acellular Dermal Matrix) audit and submit all cases

6. Training Requirements:

- Individuals should attend a recognised comprehensive training course
- There has to be evidence of acceptable results for the individual surgeon for the first 10 cases in respect to implant loss (<10%).
- If this level is not met then a further audit period would be undertaken with the same level of acceptance.
- All cases should be audited prospectively

7. Commissioning ADM assisted implant reconstruction

ADM assisted and expander procedures have the following in common:

- Implant based procedure
- Single surgical site and scar
- No donor-site morbidity
- Does not preclude further reconstruction options

As well as some important differences:

	Expander/Implant	ADM Assisted
Surgery	2 operations	1 operation (if expander not used) (*10% revision rate for "1 stage procedures")
Discharge	Usual standard of care	Drains until <30mls/day (up to 3 weeks)
Follow up	Average of 9 outpatient follow up appointments Need for repeated expansion	Reduced number of outpatient follow up appointments
Recovery time	2 procedures	Potential for 1 procedure
Cost	1 stage procedure may have potential cost advantage despite upfront loading of ADM cost	

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Appendix A. Levels of evidence

The evidence cited in the guidelines has been classified as accurately as possible into 5 levels following reference to and adaptation of the definitions provided by the Centre for Evidence Based Medicine (www.cebm.net), National Institute for Clinical Excellence Guidelines Manual (www.nice.org.uk) and the Scottish Intercollegiate Guidelines Network Guidelines Development handbook (www.sign.ac.uk):

Level I evidence is based on randomised, controlled trials (or meta-analysis of such trials) of adequate size to ensure a low risk of incorporating false-positive or false negative results.

Level II evidence is based on high-quality systematic reviews of case-control or cohort studies;

Level III evidence is based on nonrandomized, controlled or cohort studies, case series, case-controlled studies or cross-sectional studies.

Level IV evidence is based on the opinion of respected authorities or that of expert committees as indicated in published consensus conferences or guidelines.

Level V evidence expresses the opinion of those individuals who have written and reviewed these guidelines, based on their experience, knowledge of the relevant literature and discussion with their peers.

The 5 levels are not direct descriptions of quality or credibility of evidence but are a heuristic guide to the nature of the data being referenced. Generally, a randomised, controlled trial (RCT) is considered to have the greatest credibility (level I) but may have methodological flaws that diminish its value and these should be noted. Well conducted systemic reviews of case controlled or cohort studies which will have a low probability of confounding or bias are classified as level II evidence.

In general, level III studies carry less credibility than level I or II studies. However if several level III studies carried out at different times and in different places produce consistent results then a greater level of confidence can be attributed to the results.

Decisions must often be made in the absence of published evidence. In these situations it is necessary to use the opinion of experts based on their knowledge and clinical experience and to these the recommendation levels IV and V are assigned. Distinction is made between the published opinion of authorities (level IV) and the opinion of those who have contributed to these guidelines (level V). However, it should be noted that by the time level V evidence has gone through the exhaustive consensus-building and peer review process used in the preparation of these guidelines, it has achieved a level of credibility that is at least equivalent to level IV evidence.