European Journal of Surgical Oncology xxx (xxxx) xxx

Contents lists available at ScienceDirect

European Journal of Surgical Oncology

journal homepage: www.ejso.com

# Biological and synthetic mesh 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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ARTICLE INFO

*Article history:*
Received 16 April 2021
Received in revised form
16 May 2021
Accepted 19 May 2021
Available online xxx

*Keywords:*
Mesh
Biological
Synthetic
Breast reconstruction
ADM
Guideline

ABSTRACT

These guidelines have 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 (ADM), biological and synthetic mesh in breast reconstruction. The guidelines represent a consensus opinion on the optimal management of patients having biological or synthetic mesh assisted breast reconstruction informed by peer-review publications. The Guidelines should be used to inform clinical decision making. Ultimately, members of the MDT remain responsible for the treatment of patients under their care.



## Introduction

These guidelines have 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 (ADM), biological and synthetic mesh in breast reconstruction. This document supplements the publication "Oncoplastic breast surgery: A guide to good practice" which gives an in depth practical guide on all types of breast reconstruction [1,2].

## Background

Implant-based reconstruction (IBR) accounts for 53% of immediate reconstructions following mastectomy in the UK [3], the majority of these being performed with a biological or synthetic mesh [4]. In 2013 the Association of Breast Surgery (ABS) and the British Association of Plastic Reconstructive and Aesthetic Surgeons

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https://doi.org/10.1016/j.ejso.2021.05.036

(BAPRAS) published joint guidelines for acellular dermal matrix (ADM) assisted procedures [5]. Since 2013, there has been a significant increase in the volume of these procedures and in the variety of biological and synthetic meshes licensed for use [4]. Practice has also evolved to include new ways of using these devices including most recently, prepectoral IBR [6].

The perceived advantages of biological or synthetic mesh as an adjunct for implant-based breast reconstruction over traditional total submuscular techniques include improved lower pole projection and control of the inframammary fold resulting in better aesthetic outcomes [7]; the potential for single-stage direct-to-implant reconstruction, avoiding the need for tissue expansion and second procedure; reduced postoperative pain and decreased operative time [8]. Despite widespread adoption of the technique and multiple publications and systematic reviews [8–15] summarising the outcomes of mesh-assisted reconstruction, there is limited high-quality evidence to support the proposed benefits of the technique. The most recent high-quality systematic review concluded that there remains a need for well-designed studies to evaluate the impact of mesh use on the clinical and patient-reported outcomes of IBR [10].

Since the publication of this review, two small randomised clinical trials (RCTs) [16,17] and two large prospective multicentre cohort studies [4,18] comparing the outcomes of IBR with and without mesh have reported. The RCTs were both European multicentre studies comparing the outcomes of two-stage expander-implant reconstruction and single-stage direct-to-implant reconstruction with biological mesh (ADM) [16,17]. Both trials demonstrated increased complication rates in patients undergoing mesh-assisted procedures at 6 [17] and 12 [16] months following reconstruction but neither study demonstrated significant differences in patient-reported outcomes between the reconstruction groups [16,19]. The trials were criticised for failure to account for learning curve effects in the ADM group [20] and exclusion of patients undergoing implant salvage from the analysis of implant loss [21]. Furthermore, the trials included predominantly slim patients (median BMI 23) with relatively small breasts (mastectomy weight <400g) and thus are unlikely to be representative of UK practice.

Of the two large multicentre prospective cohort studies, the North American study compared the outcomes of two-stage expander-implant reconstruction with and without ADM in 1297 patients and found no differences in complication rates or patient-reported outcomes between the groups at two years following reconstruction [18]. As UK practice is now predominantly single-stage direct-to-implant using animal-derived ADM products, the generalisability of these results to the UK population should be viewed with caution.

The UK iBRA study recruited 2108 patients undergoing IBR at 81 centres between 2014 and 2016 including 1376 patients receiving mesh-assisted procedures. The study reported high rates of implant loss (9%), infection (25%), readmission (18%) and reoperation (18%) within 3 months of reconstructive surgery in all groups, irrespective of the use or type of mesh [4]. Complications rates were associated with smoking, high body mass index (BMI), longer operative time and previous radiotherapy, consistent with previously published studies [22–25]. This highlights the importance of careful patient selection in combination with meticulous perioperative practice [22,26] to optimise outcomes for patients undergoing mesh-assisted IBR procedures. Of note, despite the proposed benefits of mesh-assisted procedures, the 3-month clinical [4] and 18-month patient-reported outcomes [27] from the iBRA study were largely consistent with the outcomes of two-stage expander-implant reconstruction without mesh reported in the UK National Mastectomy and Breast Reconstruction Audit [28].

Data regarding the long-term results of mesh-assisted procedures, including patient-reported outcomes are currently lacking [29]. Single-centre case-series with long-term follow-up have been published [30,31] and have shown excellent results, but it is unlikely that these outcomes from expert centres can be extrapolated to the wider reconstructive community. Furthermore, population-based studies have shown high rates of revision in implant-based reconstruction [32] but little is known about long-term revision rates when mesh is used. Work is particularly required to explore the outcomes of mesh-assisted reconstruction following radiotherapy. A recent meta-analysis suggests rates of capsular contracture may be reduced when ADM is used, but follow up is limited and included studies are heterogenous [33] so caution is required when interpreting these results. There remains the need for high-quality clinical and patient-reported outcome data to support the practice of mesh-assisted IBR in the UK.

In 2020, 'First Do No Harm', the report of the Independent Medicines and Medical Devices Safety Review led by Baroness Julia Cumberlege was published [34]. The review aimed to examine the English healthcare system response to reports about harmful side effects from medicines and medical devices. The Report highlighted many themes relevant to breast surgery and helped inform this guidance. We would encourage all users of implanted products to read the Summary of Recommendations and Actions for Improvement https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf.

The main themes of the Cumberlege report that breast reconstructive surgeons, as users of medical devices should consider are:

- 'I was never told' – the failure of truly informed consent about the procedure, the products being used and surgical experience.
- 'Collect once, use often' and 'Collecting what matters' – Databases and Registries
- Patient safety – doing it better

Our practice is continually evolving, and it should continue to do so, however, as reconstructive surgeons we must ensure that our innovation is accompanied by appropriate evaluation and that patients are fully informed if/when a new device is being used. Fully informed consent should include discussion of local experience with the device and limitations of any available evidence supporting its use so patients may choose whether or not to undergo the procedure.

## Aims

The aims of this document are to:

i. describe the use of biological and synthetic mesh in oncoplastic breast surgery
ii. describe the clinical considerations for use of biological and synthetic mesh in implant-based breast reconstruction
iii. guide topics for discussion for informed consent for breast procedures using biological and synthetic mesh
iv. inform the content of patient information [12].
v. describe quality criteria and audit for biological/synthetic mesh in breast reconstruction procedures
vi. inform those developing and commissioning services of the identified clinical standards and quality indicators associated with the procedure

These guidelines are based on the best available peer-reviewed evidence for mesh-assisted IBR supported by expert opinion where evidence is lacking.

## Use of biological and synthetic mesh in oncoplastic breast surgery

*Role of biological or synthetic mesh in oncoplastic breast surgery*

Biological or synthetic mesh may be used in the following settings:

i. Implant-based total breast reconstruction after mastectomy; both for breast cancer patients and in women undergoing risk-reducing surgery
   a.Immediate reconstruction
   b.Total pre-pectoral or partially sub-pectoral reconstruction
ii. Revision of cosmetic concerns following breast surgery
   a. In the clinical setting of revising implant-based reconstructions e.g., correction of "bottoming out", symmastia and implant rippling
   b. Revision of cosmetic concerns following oncoplastic breast conserving surgery e.g., correction of "bottoming out" after mammoplasty or mastopexy
iii. Congenital asymmetry/deformity surgery

*Biological or synthetic mesh selection*

There are a large number of products available and the product range is rapidly evolving. There is no clear consensus on the ideal biological or synthetic mesh or evidence to inform mesh selection. The guideline group recommends consideration of the following when selecting a product:

i Biological versus synthetic
   • Biological products (e.g. ADMs) are usually animal derived. Ensure the patient is informed and comfortable with the mesh origin.
   • Synthetic mesh may be composed from absorbable and/or non-absorbable materials.
ii Evidence of complication rates for a specific product
iii Experience of using the product (surgeon, theatre team, wider clinical team, wider surgical community).
iv Ease of use. Particular consideration to evidence that prolonged operating times are associated with increased complication rates for implant-based reconstruction procedures [4].
v Cost effectiveness
vi No innovation without evaluation for products lacking short and long term evidence base.
vii All devices must have appropriate approvals and registration as a medical device through Medicines & Healthcare products Regulation Agency (MHRA) [35] in the United Kingdom.

The remainder of this document focuses on biological or synthetic mesh assisted immediate implant-based breast reconstruction techniques where the majority of the evidence is focused. Many of the topics which follow should also be considered when biological or synthetic mesh is used in other aspects of breast surgery.

## Clinical considerations for delivering biological/synthetic mesh assisted breast reconstruction

*Clinical considerations*

The following considerations supplement the recommendations made in Oncoplastic Breast Surgery: A guide to good practice [12].

i. Planned mastectomy with breast reconstruction procedure following full discussion at the diagnostic or oncoplastic multidisciplinary team meeting
ii. Discussion of the advantages and disadvantages of biological/synthetic mesh-assisted reconstruction and all other suitable oncoplastic procedures [12].

Consideration should be given to:
a. Individual patient risk-factors including smoking, BMI and previous radiotherapy [4].
b. Suitable skin envelope. Healthy skin with normal vascularity pre-operatively
c. Provision of written information, opportunity to review photos of surgical outcomes, opportunity to meet other patients where practical.
d. Patients who decline or are unable to undergo autologous tissue reconstruction (i.e., no suitable donor sites)
e. Adjuvant radiotherapy and the long-term effects this may have on different types of reconstruction (autologous vs implant based).

iii. The patient should have knowledge and acceptance that the reconstruction involves a biological/synthetic mesh.

Specific points for discussion should include:
a. Biological products are animal derived and the origin of specific mesh should be discussed
b. Whether the mesh remains permanently or is expected to be absorbed and the impact this may potentially have
c. Local experience with the mesh and the published evidence for its use including uncertainty regarding long-term clinical (e.g., need for revision surgery) and patient-reported outcomes.

iv. Knowledge and acceptance that the reconstruction involves a breast implant [12].
   a. there must be documentation that the patient has been informed of the risk of BIA-ALCL
   b. there is no set lifespan of a breast implant
   c. Patients should be aware that revisional surgery is frequent in the early stages following reconstruction
   d. that the drain may be left in-situ for up to two weeks
   e. Patients should be informed that surgery to the opposite breast is commonly necessary to achieve optimal symmetry.
v. Patients need to be informed of local complication rates when considering surgery and how complications may present post-operatively [36]. By 3 months national rates are [4];
   a. Readmission ~18%,
   b. Reoperation ~18%,
   c. Infection ~25%
   d. Implant loss ~9%.
vi. Patients opting for a single-stage procedure must be informed preoperatively of the possibility of a two-stage procedure using an expander because of possible impaired vascularisation of the skin flaps
vii. Patients should be aware that long-term results of implant-based reconstruction may deteriorate over time and patients may require subsequent planned surgery for cosmetic concerns [32]. The impact of biological/synthetic mesh on revision rates is unclear. Funding for further procedures may be limited. Cosmetic outcome of further procedures may be limited.

viii. Bilateral reconstruction. Consideration should be given to reducing operating time to minimise surgical complications [4] (e.g., dual team operating is recommended)
ix. A multifactorial approach should be utilised to minimise the complications of mesh-assisted procedures[22] [26]. Intra-operative measures include: prophylactic antibiotics, alcohol-based skin preparation, laminar flow, patient warming, minimisation of staff traffic, double glove use for implant handling, tunnelled drains and pocket washout. Combining these factors has been shown to be effective [22] but the evidence for individual components is limited [26].
x. Extended antibiotic prophylaxis – consider selective use of extended (>1 dose) antibiotic prophylaxis in those patients deemed "high risk" for infection [1,2,37–39].
xi. Units should have a written policy of infection control measures to be used in implant-based procedures.
xii. Consider negative pressure wound therapy to reduce risk of developing wound healing complications in high-risk patients [40].
xiii. Written patient information should be available (see Appendix A for suggested contents)

*Cautions*

i. Do not compromise oncological principles
   a. Consider, and discuss with patients the potential delay in adjuvant treatment, which may occur as a result of complications [41].
ii. Early aggressive/surgical management of complications
   a. Ensure suitable arrangements are available out of hours with appropriately skilled teams and patients are fully informed of 'warning signs' and how to access care, if needed [36].
   b. Early surgical intervention for skin necrosis
   c. Consider early planned clinical review
iii. Radiotherapy
   a. Patients requiring post-operative chest wall radiotherapy may have increased rates of complications [24].
   b. There is an increased risk of capsular contracture post radiotherapy. ADM may reduce rates of capsular contracture [42] but evidence is conflicting [10,33] and caution is advised.
   c. Those who have received radiotherapy prior to reconstruction have an increased risk of complications (around 1.5-fold increase in risk) [22] including capsular contracture
iv. Patient risk factors
   a. Increasing BMI increases rates of complications [4].
   b. Patients with a history of smoking, or who continue to smoke (or use nicotine containing substitutes), have a higher risk of complications including implant loss [4] (around two-fold increase in risk). The risk remains increased in ex-smokers.
   c. Estimated mastectomy weight - increased infection rate associated with weight >600gms [23,43].

## Quality criteria and audit recommendations

*Audit recommendations*

i. All surgeons performing biological or synthetic mesh assisted, implant-based reconstruction should participate in comprehensive prospective audit.
ii. All surgeons should be aware of their own and their unit complication rates.
iii. All cases should be submitted to the Breast and Cosmetic Implant Registry.
iv. All surgeons should contribute to national audits of reconstruction or appropriate research studies.
v. Patient reported outcomes should be assessed using validated measures (BREAST-Q) [44].
vi. All surgeons must undertake formal evaluation of new products, new techniques
vii. Audit recommendations for oncoplastic surgery and implant reconstruction outlined in the national oncoplastic guideline should be followed [12].

Suggested data items to consider for audit are included in Appendix B.

*Audit criteria*

The guideline team recommend the following criteria for audit. Items should include the core outcome set for breast reconstruction [45] and the recently developed core measurement set for implant-based reconstruction [44]. For each criteria the NMBRA [28] outcome has been stated, the iBRA [4] finding followed by a target standard that individual Units should aspire to, once experienced in the technique.

i. Surgical techniques should be optimised to reduce local complications following skin sparing and nipple sparing mastectomy

NMBRA outcome: 7.6% of patients returned to theatre for local complications (wound infection or skin flap necrosis requiring debridement; haematoma) during index admission
iBRA outcome: 18% of patients required return to theatre within 3 months.
Target Standard: <10% of patients requiring return to the operating theatre for local complications within 3 months of index operation.

ii. Implant loss at 3 and 12 months is assessed and audited

NMBRA outcome: 9% of immediate breast reconstruction (IBR) patients reported implant loss
iBRA outcome: 9% of patients experienced implant loss within 3 months of index operation.
Target Standard: complications leading to implant loss occur in <5% of patients 3 months.

iii. Patient experience of information and outcomes

Satisfaction with information for those proceeding with breast reconstruction.
NMBRA outcome: At 3 months, 72% of patients reported satisfaction with information provision.
50% of patients received written information about breast reconstruction
iBRA outcome:96% patients received written information.
At 3 months 92% reported satisfied with information provision.
Target Standard: 100% of patients receive written information about breast reconstruction.

## Training requirements

All surgeons new to biological/synthetic mesh assisted reconstruction techniques need training:

i. Individuals should be aware there is a recognised learning curve and be mentored for the introduction of this technique by an experienced surgeon (with audit evidence) until competency is reached
ii. There has to be evidence of acceptable results for the individual surgeon (see audit standards).
iii. All cases should be audited prospectively

## Commissioning and funding considerations for biological or synthetic mesh assisted implant reconstruction

Teams should be aware that currently there is no nationally agreed tariff in the UK for biological/synthetic mesh assisted breast reconstruction. Good quality audit data will be invaluable when negotiating re-reimbursement costs as the one-stage mesh-assisted breast reconstruction may be cost effective and potentially cost saving [46].

Units should ensure appropriate coding is used for accurate audit, long-term follow up and reimbursement.

There are now nationally agreed operation codes [47,48] (Fig. 1) for use of synthetic or biological mesh which can be used for implant reconstruction procedures. Units should ensure these are adopted into local practice.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Patient information specific to biological or synthetic mesh-assisted implant reconstruction

Written patient information should include:

1. Risks and benefits of mesh assisted implant reconstruction [36].
   a. Recovery times
   b. Delays to adjuvant therapy if a complication occurs [41].
   c. ALCL
   d. Complication rates in general by 3 months [4] (and where available local audit evidenced complication rates quoted) should include:
      i. Reoperation ~18%,
      ii. Readmission ~18%,
      iii. Infection ~25%,
      iv. Implant loss ~9%.
   e. Long term outcomes
      i. Lack of long term evidence
      ii. Likelihood of revision surgery
      iii. Likelihood of symmetrising surgery
      iv. Potential effects of adjuvant radiotherapy
2. Specific risk factors for the individual patient
3. Origins of mesh (biological (specific animal derivation) vs synthetic)
4. Information on 'early-warning' signs for complications [36].
   a. Red breast
   b. Swelling (prolonged or recurrent seroma)
   c. Systemic symptoms of infection – fever, malaise.
   d. Wound healing concerns e.g. Leakage or discolouration
5. Information on what to do in event of concerns about complications [36].
   a. How to identify a problem
   b. How to access help

Clear explanation for patients when a new product is being used.

1. Y26.6 Partial removal of mesh from organ
2. Y26.7 Total removal of mesh from organ
3. Y28.1 Insertion of synthetic mesh into organ
4. Y28.2 Insertion of biological mesh into organ
5. Y28.3 Insertion of composite mesh into organ
6. Y28.4 Insertion of mesh into organ
7. Y28.8 Other specified insertion of other material into organ
8. Y28.9 Unspecified insertion of other material into organ
9. Y36.5 Introduction of biological scaffold into organ *includes introduction of acellular dermal matrix into organ.*
10. Y36.6 Introduction of synthetic scaffold into organ.
11. Y36.7 Introduction of other scaffold into organ.

**Fig. 1.** Mesh (biological/synthetic) subsidiary 'method of operation' codes for Breast procedures OPCS 4.9 [43,44].

## Appendix B. Data Items to consider collection for audit

| | Data items to collect |
|---|---|
| Patient factors | Body mass index (BMI) |
| | Smoking |
| | Significant Comorbidities |
| | ASA |
| Oncology | Previous surgery |
| | Previous radiotherapy |
| | Indication for surgery |
| | Associated axillary surgery |
| Surgical factors | Incision used |
| | Mastectomy weight |
| | Implant data – BCIR (type and size) |
| | Mesh data – BCIR |
| | Peri-operative antibiotics |
| | - type, dose and duration |
| | Simultaneous lipofilling |
| | Operative duration |
| | Laminar flow |
| Complications (at 3 and 12 months) | Readmission |
| | Re-operation |
| | Infection/Antibiotics |
| | Wound complications |
| | Implant Loss (Reconstruction failure) |
| Adjuvant treatment | Radiotherapy |
| Further surgery | Planned procedures |
| | Unplanned procedures - cause |
| Patient reported outcomes (BREAST-Q) | Satisfaction with information |
| | Satisfaction with breasts |
| | Quality of life |

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