

Lipomodelling Guidelines for Breast Surgery

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

ABSTRACT

Guidelines on lipomodelling are required to support training and audit, inform appropriate use, and promote safety. Despite the long history of fat transfer, lipomodelling has only become technically refined and safe in the last 20 years. There is currently little prospective data on long-term outcomes. Detailed and informed assessment of patients is essential to identify those who will benefit from the technique and to minimise the risk of adverse outcomes. Provision of full preoperative information on the nature and risks of the procedure is essential, and should accompany careful assessment of patients suitability and individual risk factors. Successful lipomodelling is dependent on a meticulous technical approach. It requires thorough training of the whole operative team and provision of appropriate instrumentation. Local governance processes must be followed when introducing lipomodelling as a new procedure to an institution. As this is a relatively new technique in breast surgery outcomes should be carefully monitored and local audit undertaken.

Keywords:

Breast surgery, lipomodelling, micro fat grafting, guidelines

INTRODUCTION

Lipomodelling is the process of relocating autologous fat to change the shape, volume, consistency and profile of tissues, with the aim of reconstructing, rejuvenating and regenerating body features. The terms in current use to describe the technique are micro fat grafting, fat transfer, fat injection and lipofilling. The latter two terms are best avoided. Success depends on careful harvesting, refining and grafting of the fat. As techniques have improved lipomodelling has become more widely applied in reconstruction following breast cancer surgery, treating congenital and acquired breast deformities, and lately for cosmetic augmentation.

Use in the UK has grown without formal training programmes or assessment, and without established guidelines. This is unsatisfactory because significant complications can occur despite early advantages and there is limited data on long-term safety and outcomes.

These guidelines are therefore required to inform surgeons, patients and those who provide and commission breast services of:

- the current status of the technique
- the indications and patient selection
- the requirements for safe delivery within a service
- the standards and recommendations for training and audit

BACKGROUND AND HISTORY

Fat auto-transplantation has been extensively utilised in breast surgery. First described by Czerny in 1895, the method was adopted by others (Wredde 1915, Lexer 1917, and Passot 1930) for breast augmentation. In the 1940's and 50's breast augmentation was commonly performed with free fat and dermofat autografts and involved en bloc harvesting and placement by open surgery with long donor and graft site scars. Complication rates were high and included infection, necrosis, and extensive resorption of the transplanted fat. Long term investigation of the fate of free fat grafts from the 1950's by Peer found over 50% graft resorption at a year and correlated with the amount of fat transferred^{1,2,3}.

Stimulated by the development of liposuction, interest in free fat grafting was reignited in the 1980's. A more systematic method was then advocated to address the high complication rate, with technical contributions^{2,3,4} leading to a more rigorous approach and more predictable results.

In oncoplastic breast surgery lipomodelling has become popular in a short time, as the demand for breast reconstruction has increased and patients' expectations of a good aesthetic outcome have risen. Furthermore, clinical indications have expanded as the shift from mastectomy to breast conservation plus radiotherapy has led to a range of defects that are potentially amenable to correction by lipomodelling. There are, however, few controlled studies^{5,6,7,8,9,10} of the effectiveness and oncological safety of the technique and its longer-term aesthetic outcomes.

INDICATIONS AND PATIENT SELECTION

Publications on structural fat grafting^{2,3} describe standardised techniques for harvesting, refining and grafting fat which are accepted and adhered to by the majority of surgeons. More predictable results for fat transfer to all areas of the body are now achieved.

The main indications for lipomodelling are listed below. Although patients within these categories may be appropriate candidates for the technique, careful assessment is essential to determine that they are suitable and fit for the procedure, and full information on risks as well as benefits must be provided.

Indications: Breast Cancer Surgery and Reconstruction

- Correction of defects and asymmetry following wide local excision with or without radiotherapy^{3,6,12}
- Improvement of soft tissue coverage following implant-based breast reconstruction^{3,4,5,11,13}
- Augmentation of volume and refinement of autologous whole breast reconstruction^{3,5,11,14}
- Stimulation of neo-vascularisation of chronically ischemic irradiated tissue¹⁵
- Replacement of implants in unsatisfactory breast reconstruction where a flap is combined with an implant¹⁶

Indications: Congenital and Acquired Abnormalities

- Secondary correction of localised contour defects or volume asymmetry ^{6,17}
- Correction of chest wall abnormalities including Pectus excavatum and Poland's syndrome in males ¹⁸
- Correction of congenital breast abnormalities including female Poland's syndrome, tuberous breasts and developmental asymmetry ^{18,19}
- Correction of contour irregularities after suboptimal surgical treatment of gynecomastia

Indications: Aesthetic and Cosmetic Enhancement

- Correction of contour or volume problems after breast reduction or mastopexy ⁴
- Camouflage of implant rippling after prosthetic breast augmentation ^{3,4,5,6,16}
- Aesthetic breast enhancement with fat transfer ^{4,6,9,20}
- Replacement of volume after removal of implants inserted for aesthetic breast augmentation ^{4,6,16}
- To disguise capsular contracture ¹⁶

DEVELOPMENT AND RESEARCH

Subcutaneous fat contains adipose derived regenerative stem cells (ADRCs) which may be of therapeutic value. This has encouraged the development of cell assisted fat transfer (increased number of ADRCs) which has been postulated to improve graft survival. However, there are no reliable prospective data from controlled clinical trials as yet. Until such time this should only be carried out by surgical specialists in the context of a controlled clinical trial or a prospective audit project in centres that have the full back up of a comprehensive breast unit. It should not be used for the purpose of cosmetic breast augmentation in private clinics. An international register of cell-assisted fat transfer cases has been suggested by the Cell Society in order to generate accurate outcome data in the future and the writing group supports this initiative (www.cellsociety.com) ^{21,22,23,24,25}.

TECHNIQUE AND TRAINING

Lipomodelling is relatively new in breast surgery, yet considerable expertise has been developed already in some UK institutions amongst plastic and breast surgeons.

Where clinicians and hospitals are introducing lipomodelling as a new technique in their institution they should follow established clinical governance processes for implementing new procedures.

These guidelines aim to describe a standard methodology for the procedure along with providing recommendations on recording and auditing outcomes. The aim is to minimise clinical risk for patients and demonstrate competence for practitioners.

As with all new procedures, formal training must be undertaken, and should have the following components:

- Background theory and knowledge, including indications and complications.
- Practical skills.
- Arrangements for supervision, assistance and mentoring during local implementation.
- A whole-team approach involving the multidisciplinary team including theatre staff.
- Evidence of completion of training to an acceptable standard before commencing practice.

The National Institute for Clinical Excellence (NICE) has been notified about this procedure, and the Interventional Procedures Advisory Committee is reviewing the role of lipomodelling in breast reconstruction as part of the Institute's work programme^a.

^aThe Interventional Procedures Advisory Committee (IPAC) will consider this procedure and NICE will issue an Interventional Procedures Consultation Document about its safety and efficacy for 4 weeks public consultation. IPAC will then review the consultation document in the light of comments received and produce a Final Interventional

Procedures Document, which will be considered by NICE before guidance is issued to the NHS in England, Wales, Scotland and Northern Ireland. NICE website 08.01.2011

PATIENT ASSESSMENT, INFORMATION AND FOLLOW UP

a) Informed consent:

Informed consent is an ongoing agreement with patients about their treatment and requires full and adequate explanation of risks and benefits. Although lipomodelling is performed more frequently, patients should be made aware that they are being offered a procedure with limited knowledge of outcomes particularly in the longer term.

Patients undergoing this procedure should be informed that:

- The technique and experience of the surgeon can affect the outcome and efficacy of fat survival.
- For optimal results and to minimise complications the procedure will often need to be staged.
- Data about the procedure, and the short and long-term results will be collected for audit purposes. How this data will be used should be explained and specific consent obtained.

Written, preferably illustrated, supporting information (Appendix 2) should be provided, and the information process recorded in the medical record. For breast cancer patients the principles outlined in Oncoplastic breast surgery - A guide to good practice should be followed²⁶. All patients require detailed pre-operative information about the operative procedure, aftercare, short-term and long-term complications, and recommended follow-up schedule.

b) Pre-operative assessment:

Considerations that must be taken into account in determining fitness for surgery are ^{3,5,25}:

- General medical comorbidities that are a contraindication to repeated procedures requiring general anaesthesia. Local anaesthesia with or without sedation may be a suitable alternative.
- Smoking – it is not recommended to perform lipomodelling in smokers.
- Medical conditions such as bleeding disorders and vasospastic conditions which increase the risk of postoperative complications.
- Current use of medications such as aspirin, non-steroidal anti-inflammatory drugs, cytotoxic and immunosuppressant drugs due to associated risks of bleeding and infection.
- Availability of adequate donor sites; there must be appropriate donor sites for the amount of fat transfer required without causing damage to underlying structures and producing poor aesthetic outcomes.
- Suitability of the recipient site.
- Patients must be advised not to actively diet around the time of fat grafting.

c) Specific considerations in patients with previous breast cancer

There is no evidence that the risk of local recurrence in breast cancer patients is increased after lipomodelling ^{5,7,8,9,10}.

All breast cancer patients on whom the procedure is to be performed must be reviewed by the multi-disciplinary team in advance.

Clinical and imaging reviews should be up to date and there should be no evidence of recurrent cancer.

In patients who have had radiotherapy the acute reaction must have resolved before lipomodelling is undertaken. We advise twelve months from the last treatment session.

d) Baseline imaging

In the absence of clinical concern, the use of baseline imaging (ultrasound, mammography and/or magnetic resonance) is not advocated by the Royal College of Radiologists Breast Group (Making the best use of clinical radiology services, 6th edition, 2007, Royal College of Radiologists.). However, breast cancer patients should have an initial follow-up mammogram before commencing lipomodelling.

e) Operative issues

The procedure may be carried out either under local or general anaesthesia. Antibiotic prophylaxis and thromboprophylaxis may be appropriate depending on individual assessment and local protocols.

Fat grafting may appear to be a simple procedure. However, the success of the procedure is highly dependent on rigorous adherence to technique, and it is essential to:

- Acquire the necessary surgical skills through appropriate training.
- Understand and use the instrumentation correctly.
- Observe standard operating theatre procedure for sterility and infection control.
- Have the support of a skilled theatre team who have the relevant knowledge, training and experience.

f) Postoperative follow up

Early wound inspection is essential to exclude post op complications such as infection, necrosis and haematoma.

A three-month assessment should be made to examine the recipient and donor sites and plan further staged procedures.

Breast cancer patients should continue with routine follow-up and imaging according to local protocols, however, mammography is best avoided in the first six months after lipomodelling.

As a minimum all patients including those without breast cancer should be seen at least one year after their last procedure to determine medium-term outcomes. Staged fat transfer patients should be followed up for at least one year after the last episode of lipomodelling

TECHNIQUE

Lipomodelling is not simply a matter of injecting fat taken from one area of the body to another. Success is heavily dependent on the technique used for harvesting, preparing and grafting of the fat. Furthermore, donor site aesthetics must be considered, not only to minimise morbidity and deformity, but also to improve contour and profile, thus enhancing the appearance of the areas used. Before embarking on lipomodelling it is essential that the surgeon is trained to assess, plan and deliver an aesthetically pleasing overall outcome.

Fat should be harvested with minimal trauma to tissues using a tumescent technique without the use of hyaluronidase in the infiltrate and with the least possible exposure to air before grafting. Placing large volumes of fat in many separate small tunnels in multiple planes is time consuming. Meticulous attention to detail is essential to avoid depositing particles larger than 3mm. Depositing large volumes in a single area is associated with increased risks of fat necrosis, calcification and oil cyst formation. Fat should be deposited in the subcutaneous plane or pectoral fascial plane and not in the breast tissue itself. Observation, hands-on training and mentorship are essential before a surgeon attempts to use the technique^{2,3,5}.

In the early stages of learning the technique it is recommended that operations requiring only small volumes of fat grafting be undertaken, before progressing to grafting larger volumes of fat.

a) Recommended training components:

Before embarking on any new technique a minimum set of theoretical and practical knowledge is essential. The easiest way to acquire the necessary skills for trainees and surgeons in units where lipomodelling is established is to be trained and mentored by those surgeons who are already using the technique.

For surgeons working in units where no pre-existing expertise is available, the necessary skills can be acquired by attending appropriate courses and visits to national centres where good practice can be observed. Mentoring arrangements for the first few cases should be made and appropriate audit mechanisms put in place.

It is recognized that plastic surgery trainees receive training in the techniques and aesthetics of liposuction during their plastic surgery training. For surgeons in other specialities with no previous training in liposuction and lipomodelling, attendance at a recognised national course, more extensive hands-on training and mentoring will be required. The liposuction aspect of this technique must be regarded as an aesthetic procedure, therefore, training in a plastic surgery centre is recommended.

b) Instrumentation and key procedural steps

Successful fat grafting depends on planting very small aliquots of undamaged fatty tissue that has been harvested with low negative pressure into to a well vascularised recipient bed.

To achieve this, liposuction should be performed with blunt-tipped cannulae (maximum diameter 3 mm) with small holes near the tip.

To deposit the fat grafts, blunt-tipped small calibre infiltration cannulae (gauge-17-18; maximum diameter 1.5mm) are recommended.

The standard technique is to centrifuge the lipo-aspirate at 3000 rpm for 1 to 3 minutes to separate the fatty tissue from the bottom layer containing serum, blood, local anaesthetic and tumescent fluid and the supernatant which consists of oil that results from fat cells ruptured during liposuction or fat processing. However, centrifugation may cause cell damage and therefore it should be restricted to the minimum time necessary to achieve fat separation.

10 cc luer-lock syringes are recommended for fat aspiration and 1 to 3 cc luer-lock syringes for fat grafting^{2,3}.

A number of commercially available systems contain satisfactory instrumentation for infiltration, harvesting and centrifuging. Alternative approaches to fat graft refinement include 'jet' infiltration systems, lipodialysis systems using semipermeable membranes or filters in conjunction with low level suction. All of these systems require specific training.

c) Complications

(i) Recipient site complications^{1,2,3,5} :

- Bruising, swelling and haematoma formation.
- Altered sensation.
- Infection.
- Fat necrosis, oil cyst formation and calcifications.
- Hypertrophic scarring.
- Contour irregularities.
- Under-correction or over-correction of deformity.
- Damage to underlying structures e.g. breast implants, pneumothorax.
- Intravascular injection with fat embolism.

(ii) Donor site complications: Standard complications of liposuction.

Complications appear to be minimal with proper use of the technique. Acceptable complication rates in current experienced and competent practices are: infection 0.6-1.1%, calcifications 4.9%, fat necrosis 3-15%^{5,17}.

Postoperative donor site bruising and swelling may be reduced by using local infiltration with adrenalin solution (1:100 000).

Early identification of local sepsis is vital so that treatment can be instituted.

Fat necrosis may occur, and can be due to injection of large volumes into a single area or injecting fat into poorly vascularised areas resulting in failure of 'graft take'. Palpable masses resulting from fat necrosis may be difficult to distinguish clinically from local recurrence in breast cancer patients, and lead to a need for additional imaging and needle biopsy.

The main radiological change identified following lipomodelling is fat necrosis, with associated micro-calcification. Requests for routine mammographic surveillance after fat grafting should contain information that the procedure has been performed and the site(s) in the breast at which it was performed^{27,28,29,30,31,32}.

d) Role of imaging after breast lipomodelling

Breast cancer patients should continue clinical and mammographic follow-up by their local MDT according to local protocol. Mammography is best avoided for at least six months after fat transfer. Mammographic signs of fat necrosis are not usually visible for at least twelve to eighteen months.

In patients without a previous history of breast cancer, routine follow-up imaging is not advised, other than for population screening mammography through the NHS Breast Screening Programme.

Patients who have undergone lipomodelling may present with symptomatic or screen-detected abnormalities in the breast. They should undergo investigation in the same way that a symptomatic or screen-detected breast lesion is investigated in a patient who has not undergone this procedure. National guidelines (Best practice guidelines for the investigation of patients with breast symptoms; NHSBSP Guidelines) should be followed. Mammography and/or ultrasound may be employed according to the presenting features and the patient's age.

Patients who have undergone lipomodelling may be at increased risk of fat necrosis and subsequently more likely to have calcifications visible on mammography. These calcifications have a typical appearance and are usually and easily recognizable. However, patients need to be made aware this may lead to an increase need for biopsy^{27,28,29,30,31}.

OUTCOMES AND AUDIT

The evidence in immediate and delayed breast reconstruction is that fat grafting does not compromise cancer treatment³³. However, the UK National Mastectomy and Breast Reconstruction Audit^b has highlighted variations in treatment and outcomes, significant complication rates, and a need to improve preoperative information for patients.

Besides the need to audit both clinical and patient-reported outcomes of lipomodelling, there are some specific unanswered questions that need to be addressed:

- Could re-vascularisation of fat grafts promote growth factors within the breast and lead to an increased risk of local recurrence?
- Will early clinical and mammographic detection of recurrent disease during follow-up be compromised?
- Will breast nodularity and calcifications due to fat necrosis mask radiological change or lead to additional invasive investigation?

Whilst long-term follow up studies have suggested that fat grafting does not lead to an increased local recurrence rate or effect clinical or mammographic surveillance these series are small and additional data is required^{5,6,7,8,9,10,27,28,34,35,36,37,38,39}. See Appendix 3 for proposed data set.

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APPENDIX 1

Levels of evidence

The evidence cited in the guidelines has been classified as accurately as possible into 5 levels:

- Level I evidence is based on randomized, 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 randomized, controlled trials that are too small to provide level I evidence. These may show either positive trends that are not statistically significant or no trends and are associated with a high risk of false-negative results.
- 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.

These 5 levels of evidence do not directly describe the quality or credibility of evidence. Rather, they indicate the nature of the evidence being used. In general, a randomized, controlled trial has the greatest credibility (level I); however, it may have defects that diminish its value, and these should be noted. Evidence that is based on too few observations to give a statistically significant result is classified as level II. In general, level III studies carry less credibility than level I or II studies, but credibility is increased when consistent results are obtained from several level III studies carried out at different time points in different locations by different authors.

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. All such evidence is classified as "opinion" (levels IV and V). 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 process used in the preparation of these guidelines, it has achieved a level of credibility that is at least equivalent to level IV evidence.

APPENDIX 2

Patient Information Sheet

Lipomodelling in Breast Surgery

What is it?

Lipomodelling or fat grafting (sometimes called lipofilling or fat transfer) is a procedure used to improve the contour of the reconstructed breast or augment (increase the size of) the breasts. It involves taking fat from elsewhere in the body and injecting it into the required area. The result can give a soft, natural appearance and feel, and is minimally invasive.

How is it done?

Fat is taken from your own body, often the abdomen, thighs, buttocks or hips, in a procedure called liposuction (a term also applied to cosmetic fat reduction). It is done through small incisions in the skin. The removed fat is then concentrated and grafted with great care in tiny amounts into the area to be treated. This procedure is performed under a local or general anaesthetic in one or more sessions depending on the amount of fat grafting that is required.

Are there any side-effects or complications?

Most patients don't run into any problems but you should be as fit as possible before your surgery. You should not be actively dieting and if you smoke you should stop several weeks before surgery. You should also not be taking aspirin or anti-inflammatory medication. Swelling at the donor site can take a while to settle and this is why a compression garment is advisable. Bruising and skin discoloration can occur but this is usually temporary. The treated areas can remain numb for several weeks. Some of the grafted fat may disappear over time and the procedure may need to be repeated. Contour irregularities may occur at the donor site. Significant complications such as infections and fat clots in the blood stream are very rare.

Post-operative Recovery

The surgery is done in an operating theatre usually as a day-case or an overnight stay. You should rest for 24 hours and then increase your activity. Normal, non strenuous activity can be resumed after 2-3 days. You will have a few small stitches to close the incisions which may have to be removed in the Dressing Clinic at 7-10 days if they are not dissolvable. It is advisable to wear a compression garment over the donor site for a few weeks after surgery. This will help with the swelling and bruising and also with improving the contour of the donor area. Ensure your bra does not put pressure on the lipomodelled area. Although not an especially painful procedure, you may need to take some painkillers (do not exceed the recommended dose).

APPENDIX 3

Lipomodelling Data Form

Patient information

Name

Address

Date of birth

Sex?

Treatment reason: cancer developmental cosmetic

If cancer, previous operation and dates:

Any radiotherapy:	Y	N
Any chemotherapy:	Y	N

Medications:

Lipomodelling information sheet given:	Y	N
Preoperative imaging	Y	N
Postoperative imaging	Y	N

Lipomodelling 1/2/3 etc

Hospital

Date

Anaesthetic

Donor site

Size of cannula

Donor amount

Technique used

Amount grafted

Recipient site(s)

Follow up date

% Graft Survival

Complications

WORKING GROUP

The writing group was appointed by the Association of Breast Surgery (ABS), The British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS), and the British Association of Aesthetic Plastic Surgeons (BAAPS):

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Conflicts:

No funding was received from the writing group's National Associations or other external bodies.

E M Weiler-Mithoff has completed a prospective trial on the use of micro fat grafting in breast surgery funded by Cytori Therapeutics Inc. She has no financial interest in the company.

E M Sassoon also received funding from Cytori Therapeutic Inc for a trial on the use of micro fat grafting in breast surgery. She has no financial interest in the company. She is also Chair of the BAPRAS breast Special Interest Group.

J M O'Donoghue is a non-executive director of Plastic Reconstructive and Aesthetic Surgeons Indemnity Scheme. He has no financial interest in the company. He is also a member of a limited liability partnership (Aesthetic Advice Limited). He is also Honorary Secretary of BAPRAS.

L Martin is Honorary Treasurer of ABS.

M Lee is a Past President of ABS.

F Fatah is President of BAAPS.

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