

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

1. Introduction

Guidelines on lipomodelling are required to support training & audit, inform appropriate use, and promote safety

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.

2. Background and History

Despite the long history of techniques of fat transfer, lipomodelling has only become technically refined and safe in the last 20 years, and there is little prospective data on long-term outcomes

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 III Chan, 2 Coleman, 3 IV Delay)

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

In breast oncoplastic surgery lipomodelling has become popular in a short time, as the demand for breast reconstruction has increased and patients' expectations of a good aesthetic result 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 amenable to correction by lipomodelling. There are, however, few controlled studies (5 Delay, 6 Coleman, 7 Illouz, 8 Rigotti, 9 Zheng, 10 Fraser III) of the effectiveness and oncological safety of the technique and its longer-term aesthetic outcomes.

3. Indications and Patient Selection

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

Publications on structural fat grafting (2 Coleman, 3 Delay IV) 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 for Lipomodelling: Breast Cancer Surgery and Reconstruction:

- Correction of defects and asymmetry following wide local excision, with or without radiotherapy (3 IV Delay, 6 Coleman, 12 Delay III),
- Improvement of soft tissue coverage following implant based breast reconstruction (3 IV Delay, 5 Delay, 4 Zocci , 11 Spear, ,13 Kanchwala III)

Augmentation of volume and refinement of autologous whole breast reconstruction (3 **IV** Delay, Spear, 5 Delay, 14 **III** Sinna),

- Stimulation of neo-vascularisation of chronically ischemic irradiated tissue (15 **III** Rigotti),
- Replacement of implants in unsatisfactory breast reconstruction outcomes where a flap is combined with implant (16 **III** Missana,)

Indications for Lipomodelling: Congenital and Acquired Abnormalities:

- Secondary correction of localised contour defects or volume asymmetry (17 **IV** Gutowski, 6 **III** Coleman)
- Correction of chest wall abnormalities including Pectus excavatum and Poland's syndrome in males (18 **III** Pinsolle)
- Correction of congenital breast abnormalities including female Poland's syndrome, tuberous breasts and developmental asymmetry (18 Pinsolle, 19 **III** Del Vecchio)
- Correction of contour irregularities after suboptimal surgical treatment of gynaecomastia

Indications for Lipomodelling: Aesthetic and Cosmetic Enhancement (May not be available in the NHS)

- Correction of contour or volume problems after breast reduction or mastopexy (4 **III** Zocci)
- Camouflage of implant rippling after prosthetic breast augmentation (3 **IV** Delay, 4 Zocci, 5 Delay, 6 Coleman 16 Missana **III**,)

- Aesthetic breast enhancement with fat transfer (4 Zocci 6 Coleman, 9 Zheng, 20 III Khouri,)
- Replacement of volume after removal of implants inserted for aesthetic breast augmentation. (4Zocci, 6 Coleman 16 III Missana)
- To disguise capsular contracture (16 III Missana)

4. 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 clinical trial or a prospective audit project in centres that have the full back up of a comprehensive breast unit. 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 (cellsociety.com) (21 III Sugimachi. 22 Kitamura, 23 III Restore , 24 I Zho, 25 IV Calabrese),

5. 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

Practitioners and theatre teams must have adequate facilities, equipment and training; governance process must be followed when introducing lipomodelling as a new procedure

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

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 (Breast reconstruction using lipomodelling after breast cancer treatment)¹.

¹ The 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

6. Patient assessment, information and follow up

Provision of full information to patients on the nature and risks of the procedure is essential, and should accompany careful assessment of their suitability and individual risk factors. Arrangements for audit of outcomes must be in place.

(i) 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 their procedure, and their 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 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 followed (26 Oncoplastic guidelines)

(ii) Pre-operative assessment

Considerations that must be taken into account in determining fitness for surgery are: (3 **IV**Delay, 5 **III** Delay, 25 **IV** Calabrese)

- General medical comorbidities that are a contraindication to repeated procedures requiring general anaesthesia. Local anaesthesia with or without sedation can be an alternative to GA
- 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 damage to underlying structures and poor aesthetic outcomes
- Suitability of recipient site
- Patient must be advised not to be actively dieting at the time of fat graft and in the early postoperative period

(iii) Specific Considerations in Patients with Previous Breast Cancer

There is no evidence that the risk of cancer local recurrence in previous breast cancer patients is increased after lipomodelling. (5 Delay, 7 Illouz, 8 Rigotti, 9 Zheng, 10 Fraser **III**).

All patients on whom the procedure is to be performed must have been reviewed within the multi-disciplinary team.

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.

(iv) 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.).

Previous breast cancer patients should have had an initial follow-up mammogram before lipomodelling according to local protocols.

(v) 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.

Superficially, fat grafting appears to be a simple procedure that anybody can carry out. 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
- Use the correct instrumentation, properly
- 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

(vi) 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

7. Technique

Successful lipomodelling is dependent on a meticulous technical approach. It requires thorough training of the whole operative team and provision of appropriate instrumentation.

harvesting, preparing and grafting of the fat. Furthermore, the aesthetics of the donor sites for harvesting the graft 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 able to assess, plan and deliver an aesthetically pleasing overall outcome.

Fat should be harvested with minimal trauma to tissues and the least possible exposure to the air before grafting. Placing a large volume of fat in many tiny

separate parcels of grafts in multiple planes is time consuming; a meticulous and skillful technique is essential to avoid depositing particles larger than 3mm, which are associated with increased risks of fat necrosis, calcification and oil cyst formation. Observation and hands-on training are mandatory before a surgeon attempts to use the technique. (2 Coleman, 3 **IV**Delay, 5 **III** Delay)

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

(i) Recommended Components of Training

Before embarking on any new technique a minimum 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 in units where no pre-existing expertise is available the necessary skills for lipomodelling can be acquired by attending the appropriate courses and visits to national centres where good practice can be observed. Mentoring arrangements for the first few cases should be made until deemed competent by the mentor and appropriate audit mechanisms put in place.

Plastic surgery trainees receive training in the techniques and aesthetics of liposuction during their plastic surgery training. For surgeons 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 may be necessary.

(ii) Instrumentation and key procedural steps

Successful fat grafting depends on planting tiny separate parcels of undamaged viable fatty tissue that have been harvested with low negative pressure, within the interstitial tissues of the recipient site.

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

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

The standard technique is to centrifuge the lipo-aspirate at 3000 rpm for 1 to 3 minutes to separate the fatty tissues from the bottom layer containing serum, blood, local anaesthetic and tumescent fluid and the supernatant which consists of oil that comes from ruptured fat cells during the liposuction or the processing of the fat.

10 cc luer-lock syringes are recommended for fat aspiration and 1 to 3 cc luer-lock syringes for grafting the fat. (2 Coleman, 3 **IV** Delay)

A number of commercially available systems contain satisfactory instrumentation for harvesting, centrifuging and infiltrating the fat. Alternative approaches to fat graft refinement include lipodialysis systems using semipermeable membranes or filters in conjunction with low level suction. Additional new methods of harvesting and preparing the fat such as Body or Harvest jet are becoming available.

(iii) Complications

Recipient site complications: (1 **III** Chan, 2 Coleman, 3 **IV** Delay, 5 **III** Delay)

- Bruising and swelling, haematoma formation
- Altered sensation
- Infection
- Fat necrosis, oil cyst formation, 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

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 practice are infection 0.6-1.1%, calcifications 4.9%, fat necrosis 3-5.7-15% (5 III Delay 17 IV Gutowski,))

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 over-injection and or pooling of fat and resultant ischemia. 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 surveillance imaging radiologists should contain information that the procedure has been performed and at which site(s). (27 Pierrefeu-Lagrange, 28 Gosset, 29 Mu, 30 Carvajal, 31 Cheung, 32 III Lazzaretti)

All patients require detailed pre-operative information about the operative procedure, aftercare, short-term and long-term complications, and recommended follow-up schedule.

(iv) 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 invitation 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, following national guidelines⁴ (Best practice guidelines for the investigation of patients with breast symptoms; NHSBSP Guidelines). 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 calcification apparent upon mammography. This is often quite typical and easily recognised, however, patients must be aware this may lead to an increase need for biopsy.

(27 Pierrefeu-Lagrange 28 Gossett, 29 Mu, 30 Carvajal, 31 III Cheung)

8. Outcomes and Audit

As this is a relatively new technique in breast surgery outcomes should be carefully monitored and local audit undertaken.

The evidence on breast reconstruction, whether it is carried out as an immediate or delayed procedure, is that it does not compromise cancer treatment (32 III Malata). However the National Mastectomy and Breast Reconstruction Audit² has highlighted variation 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 in a relatively new and expanding area of use of this technique.

- 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 affect clinical or mammographic surveillance these series are small and additional data is required. (5 Delay, 6 Coleman , 7 Illouz, 8 Rigotti, 9 Zheng 2008, 10 Fraser, 27 Pierrefeu-Lagrange 28 III Gosset, 34 IV Locke, 35 III Hyakusoku 36 Sinna, 37 IV Mojallal, 38 III Cotrufo, 39 III Ogawa,)

We suggest that all patients undergoing lipomodelling should be audited locally - see appendix for recommended dataset.

² National Mastectomy and Breast Reconstruction Audit; 4th Annual Report 2011

Appendix

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 times and in different places.

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.

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Appendices

Appendix 1:

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 into 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 graft needed.

Are there any side-effects or complications?

Most patients don't run into any problems but you should be as fit as possible before the surgery not actively dieting and stop smoking.

Swelling at the donor site, as with any liposuction – this 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. Before the surgery you should not be taking aspirin or anti-inflammatory medication.

Sensation – the treated areas can remain numb for several weeks.

Some of the fat grafted may disappear over time and the procedure may need to be repeated. Contour irregularities may occur but these should settle in time.

Post-operative Recovery

The surgery is done in 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 Dressing Clinic at 7-10 days if they are not dissolvable.

It is advisable to wear a snug girdle or long-legged knickers/cycle shorts over the donor area for a few weeks. This will help with the swelling and bruising and also with the contouring of the donor area. Ensure your bra does not put pressure on the lipomodelled area.

Pain – although not an especially painful procedure, you may take your usual painkillers as required (do not exceed recommended dose).

Appendix 2:

Data Form

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

Lipomodelling 1

Hospital

Date

Anaesthetic

Donor site

Size of cannula

Donor amount

Technique used

Amount grafted and site
SHAPE * MERGEFORMAT