

Breast reconstruction using lipomodelling after breast cancer treatment

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the efficacy of breast reconstruction using lipomodelling after breast cancer treatment is adequate and the evidence raises no major safety concerns. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 There is a theoretical concern about any possible influence of the procedure on recurrence of breast cancer in the long term, although there is no evidence of this in published reports. NICE therefore encourages long-term data collection on this procedure.
- 1.3 Patient selection should be carried out by a breast cancer multidisciplinary team.
- 1.4 Breast reconstruction using lipomodelling after breast cancer treatment should only be carried out by surgeons with specialist expertise and training in the procedure.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Breast reconstruction following surgery for breast cancer may be done during the same operation or at a later date, and may involve prosthetic material (implant) alone, or autologous tissue (tissue from elsewhere in the body, usually the

abdomen, buttocks or back), or a combination of the two.

2.2 Outline of the procedure

- 2.2.1 Lipomodelling uses the patient's own fat cells to replace volume after breast reconstruction, or to fill defects in the breast following breast-conserving surgery. It can be used on its own or as an adjunct to other reconstruction techniques. The procedure aims to restore breast volume and contour without the morbidity of other reconstruction techniques. However, a degree of fat resorption is common in the first 6 months and there have been concerns that it may make future mammographic images more difficult to interpret.
- 2.2.2 With the patient under general or local anaesthesia, fat is harvested by aspiration with a syringe and cannula, commonly from the abdomen, outer thigh and/or flank. The fat is usually washed and centrifuged before being injected into the breast. Patients subsequently undergo repeat treatments (typically 2 to 4 sessions).
- 2.2.3 Commencement of lipomodelling treatment may be delayed for a variable period of time after treatment of breast cancer.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 2.3.1 In a case series of 734 procedures for breast reconstruction (880 procedures in total), the results of lipomodelling following conservative surgery were judged to be 'very good' in 50% of procedures, 'good' in 40% and 'moderately good' in 10% (based on clinical examination, photographs and patient opinion: absolute numbers not stated).
- 2.3.2 A case series of 820 patients, including 381 with asymmetry after mastectomy

and breast reconstruction, reported that the majority of patients had a 'significant improvement in their breast size and/or shape postoperatively'. Long-term breast asymmetry was reported in 4% (34 out of 820) of patients.

- 2.3.3 A case series of 69 patients (74 breasts) reported a 'good to very good' improvement in 87% (64 out of 74) of breasts and a 'moderate' improvement in 14% (10 out of 74) of breasts (assessment from photographs by 2 independent surgeons).
- 2.3.4 A non-randomised comparative study of 61 patients (62 breasts) treated by lipomodelling (n=20) or standard treatment only (n=42; not described) reported improvement in mean aesthetic results from 2.7 at baseline to 4.3 and 3.1 points respectively at 3-month follow-up ($p \leq 0.032$; evaluated using a 5-point scale: 5=very good).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as volume change, aesthetic assessment of breast shape, quality of life and body image assessments.

2.4 Safety

- 2.4.1 The case series of 734 lipomodelling procedures for breast reconstruction reported that 10 years of oncological follow-up did not reveal any increased risk of local recurrence after mastectomy or after conservative treatment. In a case series of 137 patients who had a modified radical mastectomy, 96% were free from recurrence and 98% were free from distant metastasis at 5-year follow-up (absolute figures not stated).
- 2.4.2 The case series of 880 procedures reported 1 intraoperative pneumothorax (probably caused by the transfer cannula piercing the pleura), which resolved with the insertion of a pleural drain.
- 2.4.3 The case series of 880 procedures reported local infection in less than 1% of procedures (6 out of 880); all resolved with treatment and had no impact on the final result. There was also an infection at a harvesting site in 1 case, which resolved with antibiotics.

- 2.4.4 The case series of 880 procedures reported a 3% rate of fat necrosis (absolute figures not stated). Liponecrotic cysts were reported in 7% (5 out of 74) of breasts at 3-month follow-up in the case series of 69 patients and in 5% (2 out of 43) in a case series of 37 patients.
- 2.4.5 The Specialist Advisers listed adverse events known from reports or experience as oil cysts, haematoma, calcification, donor and breast site deformity, complete resorption of fat, and uncertain findings on clinical surveillance and mammography. They raised the theoretical possibility of an increased rate of breast cancer recurrence and fat embolism.

2.5 Other comments

- 2.5.1 The Committee noted that there have been concerns about possible interference as a result of the procedure with imaging of the breast for cancer surveillance. However, it was advised that this ought not to be an issue with current techniques for lipomodelling and with expert interpretation of subsequent images.
- 2.5.2 The Committee noted that the techniques used for lipomodelling continue to evolve.
- 2.5.3 The Committee noted that devices are being introduced which aim to concentrate adipose stem cells in the tissue that is being used for lipomodelling. Further information about the outcomes of this and other adaptations of the technique of lipomodelling is desirable for guiding their future use in clinical management.
- 2.5.4 The Committee noted that joint guidelines on lipomodelling are in development and these include a dataset for a proposed national audit.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).