Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Restoring breast volume and shape after breast cancer surgery by injecting the patient's own fat

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how injecting the patient's own fat can be used in the NHS to restore breast volume and shape after breast cancer surgery. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This document is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe restoring breast volume and shape after breast cancer surgery or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The document includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 6.

What has NICE said?

This procedure can be offered routinely as a treatment option for restoring breast volume and shape after breast cancer surgery provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

There is a concern that in theory this procedure could have an effect on breast cancer returning in the long term, but there is no published evidence of this. Therefore, NICE has asked for more long-term information to be collected on this procedure.

A team of healthcare professionals who are experienced in the management of breast cancer should decide which patients should be offered this procedure. Only surgeons with specific skill and training in this procedure should carry it out.

Other comments from NICE

There were some concerns that the procedure could interfere with imaging techniques that are used to check for cancer. However, this should not be a particular issue with the current techniques, and with expert examination of the images.

This procedure may not be the only possible treatment for restoring breast volume after breast cancer.

Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Restoring breast volume and shape after breast cancer surgery by injecting the patient's own fat

The medical name for this procedure is 'breast reconstruction using lipomodelling after breast cancer treatment'.

The procedure is not described in detail here – please talk to your specialist for a full description.

Surgery for breast cancer may involve removing the whole breast (mastectomy) or part of the breast (local excision or lumpectomy). Breast reconstruction can either be done at the same time as breast cancer surgery or afterwards. This can involve artificial implants, or tissue from elsewhere in the body, or a combination of both.

Lipomodelling uses the patient's own fat cells to replace breast volume, or to shape parts of the breast, after surgery. It can be performed on its own or in addition to other techniques for reconstructing the breast. The procedure aims to improve the volume and shape of the breast, without the consequences and complications that can sometimes follow other techniques. It is common for some of the injected fat to be reabsorbed in the first 6 months.

With the patient under general or local anaesthetic, fat is taken from the belly, side or outer thigh using a syringe. The fat is usually spun and washed to remove blood and dead cells before being injected into the breast. Usually between two and four sessions are needed. Treatment may start at the same time as breast cancer surgery or later.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks this procedure is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 7 studies on this procedure.

How well does the procedure work?

In a study including 734 procedures (880 procedures in total), the results were assessed by clinical examination, photographs and patient opinion. In half of the procedures, the results were described as 'very good'. In 40% of procedures the results were 'good', and they were 'moderately good' in 10%.

In a study of 820 patients who had the procedure, including 381 with asymmetry after mastectomy and breast reconstruction, most patients had a 'significant improvement in their breast size and/or shape'. In the long term 34 patients had breasts that remained uneven in shape or size.

A study of 69 patients (74 breasts) also reported improvement following the procedure. This was described as 'good to very good' in 64 breasts and 'moderate' in 10 breasts (assessed by 2 independent surgeons from photographs).

One study of 61 patients (62 breasts) compared the results from lipomodelling with standard treatment. Both treatments resulted in an improvement, but this was significantly better in patients treated by lipomodelling.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that key success factors were change in the size and look of the breast, quality of life and body image.

Risks and possible problems

In the study including 734 procedures (880 procedures in total), after 10 years the risk of local recurrence of breast cancer was not increased. In a study of 137 patients who had a modified radical mastectomy (where the muscles in the chest wall are removed, as well as the whole breast), almost all of them had no further cancer in the breast, and the cancer had not spread to other parts of the body within 5 years.

In the study of 880 procedures, one patient had pneumothorax (air in the chest cavity) during the procedure, which was treated using a drain. Six procedures caused infection in the breast area, and one infection in the place where the fat cells were taken from. All infections were treated successfully.

In the same study, fat necrosis (or damaged fatty tissue in the breast) was reported in 3% of procedures.

In the study of 69 patients, fatty cysts were reported in 5 of 74 breasts after 3 months. Fatty cysts were also reported in a study of 37 patients, in 2 of 43 breasts.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that problems include cysts, bruising, hardening of the breast, deformity of the breast or the site the cells were taken from, the fat being reabsorbed into the body, and abnormalities detected on clinical examination or mammography. In theory, there may be an increased rate of the breast cancer returning, and fat blocking an artery.

More information about breast cancer

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may

also be able to give you further information and support. For details of all NICE guidance on breast cancer, visit our website at www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This document is about 'Breast reconstruction using lipomodelling after breast cancer treatment'. This document and the full guidance aimed at healthcare professionals are available at

http://guidance.nice.org.uk/IPG417

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service. We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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