

# Interstitial laser therapy for fibroadenomas of the breast

Interventional procedures guidance

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[nice.org.uk/guidance/ipg131](https://www.nice.org.uk/guidance/ipg131)

## 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. However, 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.

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.

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 safety and efficacy of interstitial laser therapy for fibroadenomas of the breast does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

- 1.2 Clinicians wishing to undertake interstitial laser therapy for fibroadenomas of the breast should take the following actions.
- Inform the clinical governance leads in their Trusts.
  - Audit and review all patients having interstitial laser therapy for fibroadenomas of the breast.
  - Ensure that patients understand the benign nature of fibroadenomas, and that watchful waiting is an option. Patients should be provided with clear written information and use of the Institute's [information for the public](#) is recommended.
- 1.3 This procedure should be carried out only within specialist breast services.
- 1.4 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

## 2 The procedure

### 2.1 *Indications*

- 2.1.1 A fibroadenoma is a benign solid lump of breast tissue, which is thought to result from an increased sensitivity to oestrogen. Fibroadenomas are very common and it is not unusual to have more than one. They are mostly found in young women but can occur in women of any age.
- 2.1.2 Most fibroadenomas do not enlarge after diagnosis. Some get smaller and some eventually disappear over time. These recommendations relate to options for breast fibroadenomas that do not resolve.
- 2.1.3 Once the diagnosis has been confirmed, conservative management is often agreed, with clinical review only. If the fibroadenoma persists or grows, or if the patient is anxious for it to be removed, it can be excised by a small open operation using general anaesthesia. Interstitial laser therapy is an alternative to open surgery.

## 2.2 *Outline of the procedure*

- 2.2.1 High-energy light delivered via a laser fibre is used to destroy the fibroadenoma. The fibre is positioned through a needle inserted percutaneously under local anaesthesia. The tip of the needle is positioned at the centre of the lump under ultrasound guidance. Laser energy is delivered through a pre-sterilised bare fibre passed through the needle a short distance beyond the tip. The energy is delivered in continuous wave mode for a few minutes. For larger lumps, multiple needles are inserted 1 cm apart, with a laser fibre through each.
- 2.2.2 There may be lower rates of infection with interstitial laser therapy compared with open surgery, and a more acceptable aesthetic result.

## 2.3 *Efficacy*

- 2.3.1 In a case series of 24 patients, interstitial laser therapy reduced fibroadenoma size (as assessed by ultrasound measurement) from a mean length of 25 mm at baseline to 14 mm at 3 months, 10 mm at 6 months, and 0 mm at 12 months. There were no palpable fibroadenomas in the 14 women followed-up for 12 months.
- 2.3.2 In another case series, the mean volume of the fibroadenomas in 27 women was significantly smaller 8 weeks after the procedure ( $0.68 \text{ cm}^3$  compared with  $2.17 \text{ cm}^3$  at baseline;  $p < 0.001$ ). Clinical assessment also demonstrated a significant decrease in area following interstitial laser therapy (a mean of  $1.25 \text{ cm}^2$  compared with  $2.60 \text{ cm}^2$  at baseline;  $p < 0.001$ ). However, at 8 weeks 37% (10/27) of women had a residual lump with a diameter of more than 1 cm. For more details, refer to the Sources of evidence.
- 2.3.3 The Specialist Advisors noted that the lack of material for biopsy with this procedure (in contrast to surgical excision) means that the benign diagnosis cannot be confirmed.

## 2.4 *Safety*

- 2.4.1 In a case series of 24 women who had undergone interstitial laser therapy, 83% (20/24) reported some discomfort during the procedure. Severe pain in 17% (4/24) of women led to the treatment being stopped prematurely. In this case

series and another that involved 27 women, local tenderness that lasted from 1 to 8 weeks was reported in all of the women.

2.4.2 In one of the case series, 30% (8/27) of women had skin blanching at the needle site after 80–100 seconds of the treatment, and these women later developed epithelial breakdown and hyperpigmentation in the same area (follow-up 8 weeks). In the second case series, 17% (4/24) of women had bruising that resolved within 1 week. For more details, refer to the Sources of evidence.

2.4.3 The Specialist Advisors noted that the reported adverse events include local burns at the needle site, and that the theoretical complications include local infection, and bleeding if the needle strikes a blood vessel.

## 2.5 *Other comments*

2.5.1 It was noted that there are variations in the technique that have potentially different efficacy profiles.

Andrew Dillon  
Chief Executive  
June 2005

## 3 Further information

### *Sources of evidence*

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of interstitial laser therapy for fibroadenomas of the breast', December 2004.

### *Information for patients*

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

## 4 Changes since publication

As part of the NICE's work programme, the current guidance was considered for review in June 2009 but did not meet the review criteria as set out in the IP process guide. This guidance therefore remains current.

23 January 2012: minor maintenance.

## 5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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## *Endorsing organisation*

This guidance has been endorsed by Healthcare Improvement Scotland.