

Radially emitting laser fibre treatment of an anal fistula

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 Recommendations

- 1.1 Current evidence on the safety and efficacy of radially emitting laser fibre treatment of an anal fistula is limited in quantity and quality. Therefore, although there are no major safety concerns, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to do radially emitting laser fibre treatment of an anal fistula should:
- Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public on radially emitting laser fibre treatment of an anal fistula is recommended.
 - Audit and review clinical outcomes of all patients having radially emitting laser fibre treatment of an anal fistula. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).
- 1.3 The procedure should only be done by clinicians experienced in cannulating fistulas, and who are trained in the use of lasers.
- 1.4 Further research should report details of patient selection, including fistula size, recurrence rates in the medium and long term, and quality-of-life outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 An anal fistula is an abnormal tract between the anal canal and the skin around the anus. It may cause symptoms such as pain or discomfort in the anal area, and leakage of blood or pus. It usually results from previous anal abscesses (cryptoglandular), and can be associated with other conditions such as inflammatory bowel disease and cancer.
- 2.2 Anal fistulas can be classified according to their relationship with the external sphincter. Intersphincteric fistulas are the most common type and cross only the internal sphincter. Trans-sphincteric fistulas pass through the internal and external sphincter.

Current treatments

- 2.3 Treatment of anal fistulas commonly involves surgery. The type of surgery depends on the location and complexity of the fistula. For intersphincteric and low trans-sphincteric anal fistulas, the most common treatment is a fistulotomy or laying open of the fistula track. For deeper fistulas that involve more muscle, and for recurrent fistulas, a seton (a piece of suture material or rubber sling) may be used, either alone or with fistulotomy. Setons can be loose (designed to drain the sepsis but not for cure), or snug or tight (designed to cut through the muscles in a slow controlled fashion). Fistulas that cross the external sphincter at a high level are sometimes treated with a mucosal advancement flap or other procedures to close the internal opening. Another less commonly used option for treating anal fistulas is to fill the track with either a plug or paste; for example, 1 type of filler is fibrin glue (a solution of fibrinogen and thrombin).

The procedure

- 2.4 Radially emitting laser fibre treatment of an anal fistula can be done with the patient under regional or general anaesthesia. With the patient in lithotomy position, the external and internal openings of the fistula tract are identified. The fistula is then catheterised using a probe and cleaned by irrigation. Under ultrasound guidance, a radially emitting laser fibre is advanced from the external to internal orifice, activated and gradually withdrawn at about 1 mm/second. The aim is to cause destruction and sealing of the fistula tract, allowing primary closure. The procedure may be used with techniques that close the internal orifice of the tract such as an advancement flap.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 7 case series, and is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: fistula closure, resolution of symptoms, quality of life and recurrence.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: incontinence, abscess, pain, anismus, bleeding and urinary retention.
- 3.4 One commentary from a patient who had experience of this procedure was received, which was discussed by the committee.

Committee comments

- 3.5 The committee was informed that it can be difficult to assess whether the fistula is closed without using imaging.
- 3.6 The committee was informed that this procedure is likely to be less effective in wider fistula tracts.

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Endorsing organisation

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