NICE National Institute for Health and Care Excellence

NICE guidance

Collagen paste for closing an anal fistula

HealthTech guidance
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www.nice.org.uk/guidance/htg512

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.

Contents

This guidance replaces IPG648.

1 Recommendations

1.1 Current evidence on the safety and efficacy of collagen paste for closing an anal fistula is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should report details of patient selection, the type of fistula treated, how the internal fistula opening was closed, and long-term outcomes including recurrence and the need for reoperation.

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 usually results from previous anal abscesses (cryptoglandular) and can be associated with other conditions such as inflammatory bowel disease and cancer. It may cause symptoms such as pain or discomfort in the anal area, and leakage of blood or pus. 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

2.2 Treatment of anal fistulas usually 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 procedure is a fistulotomy or laying open of the fistula tract. 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 option for treating an anal fistula is to fill the tract with a plug or glue.

The procedure

2.3 The use of collagen paste for closing an anal fistula is done using general

anaesthesia and with the patient in the lithotomy position. The fistula tract is de-epithelised and granulation tissue is removed, then it is cleaned with dilute hydrogen peroxide followed by saline. A guiding catheter is connected to a syringe containing the paste and the other end is inserted into the external opening of the fistula. The paste is injected into the fistula until it is visible at the internal opening, and then the guiding catheter is slowly withdrawn. The internal opening of the fistula is closed using resorbable stitches. The external opening is partially closed, using resorbable stitches if needed, to allow any inflammatory fluid to drain out without allowing the collagen paste to escape.

2.4 The paste fills the exact shape of the tract, which is intended to reduce the risk of it being expelled from the body when defaecating.

2.5 It is a less invasive procedure than traditional surgery and the aim is to allow the fistula to heal while preserving sphincter function.

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 6 sources, which was discussed by the committee. The evidence included 1 non-randomised comparative study and 5 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: ablation of fistula, prevention of recurrence and the need for further surgery, and improved quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding and infection.

3.4 Four commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

3.5 The committee was informed that the fistula tract needs to be appropriately prepared before the collagen paste is applied.

3.6 The committee was informed that having this procedure does not affect future treatment options.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 648 has been migrated to HealthTech guidance 512. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.