Surgical repair of anal fistula with a bioprosthetic plug

This leaflet is about when and how a bioprosthetic plug can be used in the NHS to surgically repair anal fistula. 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.

This leaflet 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 anal fistula or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet 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?

Although there are no major safety concerns about this procedure, there are still uncertainties about how well it works.

NICE has encouraged doctors who want to use the procedure to treat anal fistula to ask the patient to take part in a research study (clinical trial) called the Fistula-in-Ano Trial (FIAT). If doctors want to use the procedure outside the clinical trial, they should make sure that extra steps are taken to explain the uncertainty about how well it works. This should happen before the patient agrees (or doesn’t agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens after the procedure.

The procedure should only be carried out by surgeons with specific training in the procedure.

NICE may review the procedure if more evidence becomes available.

Other comments from NICE

NICE noted that anal fistulae can cause distress to people and are difficult to treat successfully. NICE recognised the potential usefulness of bioprosthetic plugs in treating anal fistulae, as long as further evidence shows that they work in large numbers of patients. NICE also noted that magnetic resonance imaging scans are potentially valuable in diagnosing some fistulae and assessing the results of treatment.
Surgical repair of anal fistula with a bioprosthetic plug

The medical name for this procedure is ‘closure of anal fistula using a suturable bioprosthetic plug’. Bioprosthetic means that the plug is made of a material that has come from an animal, usually a pig.

An anal fistula is an abnormal small tunnel that forms a connection between the anal canal (back passage) and the skin near the anus. A fistula usually results from a previous anal abscess that has not healed properly, but it can also be linked to other conditions such as Crohn’s disease. An anal fistula may cause symptoms such as pain or discomfort around the anus and leakage of blood or pus from the fistula.

Several different types of surgery may be performed to encourage healing.

In this procedure a specially designed ‘plug’ is inserted into the fistula and stitched in place. The aim is to seal off the fistula where it joins with the bowel while still allowing any pus to drain out as the fistula heals and new tissue grows.

The procedure is performed with the patient under general anaesthesia. The fistula tract is identified using a probe or imaging scans, and it may be cleaned. Then the surgeon pulls a cone-shaped plug into the inner opening of the fistula tract until it blocks it, and then the plug is stitched into place. The plug acts as a scaffold, into which new tissue can grow.
What does this mean for me?

If your doctor has offered you surgical repair of anal fistula with a bioprosthetic plug, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss uncertainty about how well it works with you. Your doctor may talk with you about the clinical trial and ask you if details of your procedure can be used to help collect more information about this procedure. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

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?
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 8 studies on this procedure.

How well does the procedure work?

In a study of 90 patients, the fistula had healed in 37 out of 45 patients who had the bioprosthetic plug and in 29 out of 45 patients who had a different procedure (called endorectal advancement flap, in which a flap of tissue is sutured over the fistula opening), when their progress was checked after 6 months.

In 2 other studies that checked patients’ progress after 3 months, the fistula had healed in 16 out of 27 patients in one study and 14 out of 43 patients in the other study. Across the 3 studies, the healing rates ranged from 32% to 82%.

In the study of 90 patients, patients who had the bioprosthetic plug had higher quality of life scores than those who had the advancement flap procedure (85.9 compared with 65.3).

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 the main aim of the procedure is to heal the fistula (measured by clinical examination and magnetic resonance imaging scans).

Risks and possible problems

In a study of 80 patients, 5 out of 37 who had the bioprosthetic plug procedure were treated with antibiotics afterwards because of pain and increased drainage from the fistula.

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 possible problems include formation of a new abscess and the plug becoming dislodged.

**More information about anal fistula**

NHS Choices ([www.nhs.uk](http://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, visit our website at [www.nice.org.uk](http://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 leaflet is about ‘closure of anal fistula using a suturable bioprosthetic plug’. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG410

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.