

Treating faecal incontinence with an artificial sphincter inserted through a cut in the abdomen

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

This leaflet is about when and how an artificial sphincter inserted through a cut in the abdomen can be used in the NHS to treat people with faecal incontinence. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech 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 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 faecal incontinence 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?

There is not much good evidence about how well this procedure works or how safe it is. In addition, the available evidence is only based on small numbers of patients. If a doctor wants to use an artificial sphincter inserted through a cut in the abdomen to treat faecal incontinence, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. 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 to the patient after the procedure.

Other comments from NICE

NICE noted that the technology used was modified during the only study that was available. Further improvements are likely to happen as the technology used in this procedure improves.

This procedure may not be the only possible treatment for faecal incontinence. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

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The medical name for this procedure is 'transabdominal artificial bowel sphincter implantation for faecal incontinence'. The word 'transabdominal' means that the implant is inserted through a cut in the patient's abdomen, instead of through the anus (back passage).

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

Faecal incontinence is when a person loses the ability to control their bowel movements, resulting in unplanned leakage of faeces. Faecal incontinence may have many different causes. It can be distressing and can severely affect everyday life.

Initial treatment for faecal incontinence usually includes antidiarrhoeal medication and dietary management. This may be followed by pelvic floor muscle training or biofeedback therapy, usually given by a specialist physiotherapist or nurse. If these treatments fail or are not suitable, surgery to repair the anal sphincter may be recommended. Other options that may be suitable for some people include sacral nerve stimulation, graciloplasty (creation of a new sphincter from other suitable muscles), a colostomy, or implantation of an artificial anal sphincter (implanted either through the anus or abdomen).

The aim of this procedure is to treat faecal incontinence with an artificial sphincter inserted through a cut in the abdomen. The procedure is done with the patient under a general anaesthetic. The surgeon makes a cut in the patient's abdomen and places a circular cuff around the bowel. The cuff is filled with fluid and sits tightly around the bowel, keeping it closed. A tube runs from the cuff to a control pump which is implanted under the skin.

When the cuff is full, the pressure keeps the bowel closed. When the patient wants to empty their bowel, they press the control pump's button under their skin. This empties the cuff so the bowel can empty. Afterwards, the patient presses the control pump's button again to expand the cuff and close the bowel.

What does this mean for me?

If your doctor has offered you this procedure for faecal incontinence, 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 the possible benefits and risks with you. 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?

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 one study on this procedure.

How well does the procedure work?

In a study of 12 patients, the implant was working successfully in 9 patients when they were reviewed almost 5 years after the procedure. Five of the 9 patients needed further surgery to repair problems with the artificial sphincter implant. In the study, a faecal incontinence score was used in 10 patients. Faecal incontinence was scored out of 20 (worst possible incontinence). Before the procedure the average score was 16, but after the procedure the average score had improved to 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 aims of the procedure are to restore faecal continence, prevent mucus leakage and improve quality of life.

Risks and possible problems

In the study of 12 patients, the implant had to be removed because of complications that affected 3 patients: 2 patients developed infections and 1 patient developed inflammation of the intestines.

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 infection, the implant becoming dislodged, problems in the blood supply to the bowel and injury to the rectum caused by the implant. One adviser said that repeat surgery to correct problems would be more difficult after this procedure, compared with the procedure in which the implant is inserted through the anus.



More information about faecal incontinence

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.

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. This 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 'Transabdominal artificial bowel sphincter implantation for faecal incontinence'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG177

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1730).

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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