

Artificial anal sphincter implantation

1 Guidance

- 1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation 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 artificial anal sphincter implantation should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
 - Audit and review clinical outcomes of all patients having artificial anal sphincter implantation.
- 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.
- 1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence.

2 The procedure

2.1 Indications

- 2.1.1 The causes of faecal incontinence are diverse. Existing treatment options include medical therapy, biofeedback techniques and surgery in selected patients. Surgical treatments include sphincter repair, sacral nerve stimulation, encirclement procedures and muscle transposition (for example, dynamic graciloplasty). Some patients may require a colostomy if other treatments fail.

2.2 Outline of the procedure

- 2.2.1 Implantation of an artificial anal sphincter is used to treat severe faecal incontinence. In this procedure, a fluid-filled cuff is implanted around the anal canal. Tubing from the cuff is channelled under the skin of the perineum and connected to a control pump placed subcutaneously in the scrotum or labia. The control pump is connected by tubing to a pressure-regulating balloon implanted in the abdominal wall. The cuff simulates the natural function of the sphincter muscle; when the fluid is displaced from the cuff to the balloon via the patient-controlled pump, defaecation can take place. Once defaecation is complete, the fluid is slowly returned to the cuff and continence is again achieved. For more details, refer to the Sources of evidence (see overleaf).

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

2.3 Efficacy

- 2.3.1 No controlled studies were identified. Some of the studies identified were small and some had high losses to follow-up. Among the studies identified, removal of the artificial sphincter system was required in 19% (10/53) to 41% (7/17) of patients. In patients who had not undergone explantation, all the studies showed improvement in continence. However, different measures of continence were used in the studies. The studies that reported manometric results showed increased mean anal pressures after implantation. For more details, refer to the Sources of evidence (see right).
- 2.3.2 The Specialist Advisors considered the main efficacy concern to be the frequent need to remove the implanted artificial sphincter.

2.4 Safety

- 2.4.1 The largest study identified reported that device-related complications occurred in 86% (99/115) of patients. The most common adverse events reported in this study were: infection 33% (38/115); pain 32% (37/115); erosion 21% (24/115); faecal impaction 18% (21/115); faecal incontinence 18% (21/115); constipation 17% (20/115); surgical injury 13% (15/115); wound problems 10% (11/115); difficult evacuation 9% (10/115); and wound dehiscence 9% (10/115). For more details, refer to the Sources of evidence
- 2.4.2 The Specialist Advisors considered the main safety concerns to be infection, erosion and evacuation difficulties.

2.5 Other comments

- 2.5.1 The procedure may have a place in the treatment of patients who are unsuitable for sacral nerve stimulation.
- 2.5.2 There is a significant rate of complications, such as infection, cuff erosion, wound dehiscence and haematoma, and patients may require revisional surgery or removal of the device. Fully informed consent is therefore particularly important.

Andrew Dillon
Chief Executive
June 2004

Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from www.nice.org.uk/IPG066publicinfo

Sources of evidence

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

Interventional procedure overview of artificial anal sphincter implantation, November 2002

Available from: www.nice.org.uk/ip128overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0597. *Information for the Public* can be obtained by quoting reference number N0598 for the English version and N0599 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG066distributionlist

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