

# Insertion of an annular disc implant at lumbar discectomy

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg506](http://www.nice.org.uk/guidance/ipg506)

## 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 insertion of an annular disc implant at lumbar discectomy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake insertion of an annular disc implant at lumbar discectomy should take the following actions:
  - Inform the clinical governance leads in their NHS trusts.
  - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 NICE encourages further research on insertion of an annular disc implant at lumbar discectomy, particularly comparative trials. All studies should report details of patient selection and recurrence rates.
- 1.4 Clinicians should enter details about all patients undergoing insertion of an annular disc implant at lumbar discectomy onto the British Spine Registry and review clinical outcomes locally.

# 2 Indications and current treatments

- 2.1 Lumbar disc herniation occurs when the nucleus pulposus of an intervertebral disc protrudes through a tear in the surrounding annulus fibrosus. Symptoms include pain in the back or leg, and numbness or weakness in the leg. Serious neurological sequelae may sometimes

occur.

- 2.2 Conservative treatments include analgesics, non-steroidal anti-inflammatory medication and physical therapy. Epidural corticosteroid injections can also be used to reduce nerve pain in the short term. Lumbar discectomy is considered if there is evidence of severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy or minimally invasive alternatives using percutaneous approaches.
- 2.3 Lumbar discectomy usually leaves a hole in the annulus fibrosus through which the nucleus herniated, which may lead to reherniation and progressive loss in disc height.

## 3 The procedure

- 3.1 Insertion of an annular disc implant at lumbar discectomy aims to reduce the incidence of recurrent herniation and the degree of intervertebral disc collapse.
- 3.2 With the patient under general anaesthesia, the herniated disc material is removed and the annular disc device is implanted. The device typically contains a metallic bone-anchoring component and a woven polymer mesh. The bone-anchoring component is inserted using a mallet and tamp into one of the vertebral bodies adjacent to the discectomy site, and the woven mesh component is inserted into the annular disc defect, so covering the residual nucleus pulposus. Fluoroscopy may be used to guide the procedure.

## 4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 A non-randomised comparative study of 102 patients (30 patients treated by discectomy plus annular disc implant and 72 patients treated

by discectomy only) reported no reherniations in the implant group within 2 years after surgery and 5 reherniations in the discectomy-only group: 3% (2/72) within 3 months and 4% (3/72) between 4 months and 2 years after surgery (level of significance not stated). A non-randomised comparative cohort study of 76 patients (30 patients from the same implant cohort as in the previous study and 46 patients treated by discectomy only) reported no reherniations 2 years after surgery in the implant group and 7% (3/46) in the discectomy-only group (no significant difference).

- 4.2 The non-randomised comparative study of 102 patients reported improvement in Oswestry Disability Index (ODI) scores in both groups. In the implant group, the ODI score decreased from 62.7 before surgery to 31.4 after 6 weeks and 11.6 after 24 months. In the discectomy-only group, the ODI score decreased from 49.4 before surgery to 30.7 after 6 weeks and 19.8 after 24 months. The scores were significantly different between the 2 groups at baseline (before surgery) ( $p=0.0004$ ) but not at 6 weeks and 24 months.
- 4.3 The non-randomised comparative study of 102 patients reported that back pain scores and leg pain scores (both measured on 100-point visual analogue scales, with higher scores indicating more severe pain) improved in both groups. Back pain scores improved from 66.3 before surgery to 10.5 after 24 months in the implant group and from 43.1 to 19.1 in the discectomy-only group (level of significance not stated). Leg pain scores improved from 79.8 before surgery to 8.9 after 24 months in the implant group and from 58.8 to 21.2 in the discectomy-only group (level of significance not stated). The scores for back and leg pain were significantly different between the 2 groups at baseline (before surgery;  $p\leq 0.0001$ ). The scores for leg pain (but not for back pain) were significantly different between the 2 groups at 12 months and 24 months ( $p<0.05$ ).
- 4.4 The non-randomised comparative cohort study of 76 patients reported a mean loss of disc height from 8.60 mm to 7.63 mm (0.97 mm loss) in the implant group compared with 8.30 mm to 6.90 mm (1.40 mm loss) in the discectomy-only group 12 months after surgery ( $p=0.054$ ). A case series of 45 patients reported a decrease of the mean disc height to 93% of

baseline 12 months after surgery ( $p < 0.01$ ).

- 4.5 The specialist advisers identified a key efficacy outcome as recurrence of herniation in the long term.

## 5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Incidental durotomy (potentially causing cerebrospinal fluid leakage and complications such as headache) occurring during disc fragment removal was reported in 1 patient treated by discectomy plus annular disc implantation and in 1 patient treated by discectomy only in a non-randomised comparative study of 102 patients (30 patients treated by discectomy plus annular disc implant and 72 patients treated by discectomy only; level of significance not stated). Incidental durotomy was reported in 1 patient treated by discectomy plus annular disc implantation and in 1 patient treated by discectomy only in a non-randomised comparative cohort study of 76 patients (30 patients from the same implant cohort as in the previous study and 46 patients treated by discectomy only; level of significance not stated).
- 5.2 Suspected discitis 56 days after surgery was reported in 1 patient treated by discectomy plus annular disc implantation and in none of the patients treated by discectomy only in the non-randomised comparative cohort study of 76 patients (level of significance not stated). The infection was successfully treated by intravenous antibiotics.
- 5.3 Reoperations were reported in 3 patients treated by annular disc implantation after discectomy in a case series of 45 patients: 1 was a symptomatic reherniation 4 months after surgery because the device was implanted too deep into the disc space, 1 was a contralateral herniation 3 weeks after surgery possibly caused by the implant, and 1 was for excessive scar tissue 5 months after surgery.
- 5.4 The specialist advisers listed additional theoretical adverse events as

haematoma, cauda equina damage, implant displacement causing nerve root damage, pain, numbness, weakness and neurological compression.

## 6 Further information

6.1 For related NICE guidance, see the [NICE website](#).

### Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

### Update information

#### Minor changes since publication

**December 2014:** Minor maintenance.

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### Endorsing organisation

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