NICE National Institute for Health and Care Excellence

NICE guidance

Prosthetic intervertebral disc replacement in the lumbar spine

HealthTech guidance
Published: 22 July 2009

www.nice.org.uk/guidance/htg197

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 IPG100 and IPG306.

1 Recommendations

1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated.

1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery.

2 The procedure

2.1 Indications and current treatments

2.1.1 Symptomatic degenerative disc disease of the lumbar spine occurs when the intervertebral discs supporting the vertebrae lose their elasticity. This can cause partial disc prolapse, which may be associated with chronic lower back and radicular pain.

2.1.2 Conservative treatments include analgesics, non-steroidal anti-inflammatory medication and physical therapy. Epidural steroid injections can also be used. Interventions for people with chronic intractable pain or neurological complications include removal of the protruding disc (discectomy) and/or spinal fusion.

2.2 Outline of the procedure

2.2.1 Artificial intervertebral discs are mobile implants that are inserted between the vertebrae. They are designed to resolve symptoms associated with disc degeneration and to reduce disc degeneration between adjacent lumbar vertebrae.

2.2.2 With the patient under general anaesthesia, the intervertebral space is accessed through an abdominal incision using a transperitoneal or retroperitoneal approach. The damaged disc is partially or fully removed and the implant inserted, taking care to ensure that the size of the replacement disc and its position within the intervertebral space are optimised to promote osseous integration and to maximise disc mobility and patient comfort. Multiple discs can be replaced during the same procedure.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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 overview.

2.3.1 A randomised controlled trial (RCT) of 304 patients (205 treated with a prosthetic lumbar disc and 99 with spinal fusion) used the Oswestry Disability Index (ODI) to assess outcomes. The RCT reported significantly greater improvement in ODI score from baseline in patients treated by prosthetic disc implantation compared with spinal fusion at 6-week, 3-month, and 6-month follow-up (absolute figures and significance not stated). At 12-month and 24-month follow-up, the differences between the two patient groups in ODI scores from baseline was no longer significant (absolute figures not stated; p=0.14, p=0.54, respectively).

2.3.2 An RCT of 236 patients (161 treated with a prosthetic lumbar disc and 75 with spinal fusion) reported that mean quality of life scores (using the Short Form-36 questionnaire) improved by 87% in the prosthetic disc group compared with 70% in those who underwent spinal fusion (p=0.004) at 3-month follow-up. This difference was no longer significant at 24-month follow-up (p=0.09).

2.3.3 A case series of 106 patients treated with a prosthetic lumbar disc reported that 42% (45 out of 106) had 'excellent', 40% (42 out of 106) 'good', 8% (8 out of 106) 'fair', and 10% (11 out of 106) 'poor' clinical outcomes (on a 4-grade Stauffer–Coventry scale from poor [no improvement or worse than preoperative condition] to excellent [no pain, treatment or medications]) at a mean follow-up of 13 years. In the same study, 90% (86 out of 96) of patients eligible for work at baseline had returned to work, and 78% (28 out of 36) had returned to manual labour (mean follow-up 13 years).

2.3.4 Specialist Advisers listed key efficacy outcomes as pain relief measured by a visual analogue scale or ODI, disability, return to work, quality of life and reduced need for additional procedures.

2.4 Safety

2.4.1 In an RCT of 67 patients, vertebral endplate fracture requiring further surgery occurred in 2% (1 out of 44) of patients treated with prosthetic intervertebral discs in the lumbar spine. None of the 23 patients treated by spinal fusion had

this complication.

2.4.2 The RCT of 304 patients reported that the rate of major neurological adverse events (not otherwise described) was higher after fusion surgery (5.4%) than after prosthetic disc implantation (2.4%) at 42-day follow-up (absolute figures and significance not stated).

2.4.3 A non-randomised controlled study of 688 patients reported a need for further surgery within 2 years in 9% (52 out of 589) of patients treated with prosthetic lumbar discs compared with 10% (10 out of 99) of patients treated by lumbar fusion ($p=0.7$).

2.4.4 A systematic review of 27 uncontrolled case series totalling 2,490 patients reported that intervertebral disc disease (defined as clinically significant degeneration) occurred at an adjacent level in 14% (173 out of 1,216) of patients treated by lumbar fusion compared with 1% (7 out of 595) of patients treated with prosthetic lumbar discs ($p<0.001$; follow-up varied between studies).

2.4.5 The RCT of 236 patients reported that infection (not otherwise described) had occurred in 3% (2 out of 75) of patients treated by lumbar fusion and 0% (0 out of 161) of patients treated with prosthetic lumbar discs at 2-year follow-up (significance not stated).

2.4.6 The Specialist Advisers listed anecdotal or published adverse outcomes as vascular injury, spinal endplate fracture, retrograde ejaculation, failure to control symptoms, device subsidence and wear debris from the device. The Specialist Advisers considered theoretical adverse events to include nerve injury (including cauda equina injury), bowel injury, haemorrhage, infection, impaired bladder function and device failure requiring revision surgery.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 306 has been migrated to HealthTech guidance 197. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8068-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.