

Prosthetic intervertebral disc replacement in the lumbar spine

This document replaces previous guidance on prosthetic intervertebral disc replacement (interventional procedure guidance 100).

1 Guidance

- 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.

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, available at www.nice.org.uk/IP126aoverview

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. 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 the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.3 Efficacy

- 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% (45/106) had 'excellent', 40% (42/106) 'good', 8% (8/106) 'fair', and 10% (11/106) '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% (86/96) of patients eligible for work at baseline had returned to work, and 78% (28/36) 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% (1/44) 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% (52/589) of patients treated with prosthetic lumbar discs compared with 10% (10/99) of patients treated by lumbar fusion ($p = 0.7$).
- 2.4.4 A systematic review of 27 uncontrolled case series totalling 2490 patients reported that intervertebral disc disease (defined as clinically significant degeneration) occurred at an adjacent level in 14% (173/1216) of patients treated by lumbar fusion compared with 1% (7/595) 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% (2/75) of patients treated by lumbar fusion and 0% (0/161) 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.

3 Further information

- 3.1 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG306publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1904 for this guidance or N1905 for the 'Understanding NICE guidance'.

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

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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