

Non-rigid stabilisation procedures for the treatment of low back pain

1 Guidance

- 1.1 Limited evidence suggests that non-rigid stabilisation procedures for the treatment of low back pain provide clinical benefit for a proportion of patients with intractable back pain. Current evidence on the safety of these procedures is unclear and involves a variety of different devices and outcome measures. Therefore, these procedures should only be used with special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake non-rigid stabilisation techniques for the treatment of low back pain should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the benefits of these procedures and the alternative treatment options, and provide them with clear written information. In addition, use of the Institute's 'Understanding NICE guidance' is recommended (available from www.nice.org.uk/IPG183publicinfo).
 - Audit and review clinical outcomes of all patients undergoing non-rigid stabilisation procedures for the treatment of low back pain.
- 1.3 Publication of further research will be useful provided that the outcome measures and comparators are well defined. The Institute may review the procedure upon publication of further evidence.

- reduction of spinal disc height and spinal facet joint arthrosis. The back pain is thought to arise from minor abnormal movements in disturbed joints, and it may be aggravated by normal activities.
- 2.1.2 Acute low back pain can be treated by muscle relaxants or analgesic therapy. Chiropractic intervention and posture training can limit episodes of acute pain. Spinal rehabilitation, which may include components such as education, lifestyle change, weight loss, general fitness and specific low-back training exercises, may be required. Injection therapy including epidural injections and steroid injections into the facet joint may be used.
- 2.1.3 Surgery may be appropriate for severe life-limiting chronic low back pain refractory to conservative interventions. There are a number of operations designed to immobilise painful segments by bony fusion. Solid spinal fusion cannot be reversed and abnormal load patterns may cause later problems in adjacent parts of the spine. Insertion of a prosthetic intervertebral disc is an alternative that attempts to create comfort while preserving lumbar mobility and reducing long-term adjacent degenerative change.

2.2 Outline of the procedure

- 2.2.1 In non-rigid (otherwise known as flexible or dynamic) stabilisation of the lumbar spine, movement and load bearing of a spinal motion segment are supported without fusing the segment in question. There are a range of systems that fulfil this function. These systems intend to restrict motion in the direction that produces pain but allow for a full range of motion in other directions. These procedures may have a role as treatment between medical symptom control and the more invasive procedure of spinal fusion.

2 The procedure

2.1 Indications

- 2.1.1 Chronic low back pain is most often the result of degenerative change, which affects everyone to some extent with increasing age. This change causes dehydration of the intervertebral discs,

Interventional Procedure Guidance 183

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. 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.3 Efficacy

- 2.3.1 In a case series of 83 patients (the majority with spinal stenosis) who had the procedure, 48% (35/73) were totally incapacitated at baseline but only 3% (2/73) remained so at a mean follow-up of 38 months. Disability scores fell from a baseline of 55% to 23% at the same follow-up point. In a smaller series of 31 cases followed up to at least 2 years, 67% of patients reported that back symptoms had resolved or improved, but 3% reported that their symptoms had worsened.
- 2.3.2 In a study that compared a non-rigid stabilisation system with fusion, patients treated with a ligament system had a greater range of movement at the L4–L5 level (4.3° change from baseline) than patients treated with fusion (0.4°) ($p < 0.05$). X-ray evaluation showed significantly less disc deterioration at the L2–L3 level with non-rigid stabilisation than with fusion. However, the difference at other levels was not significant. In a case series of 59 patients assessed using a visual analogue scale (1–100), low back pain was reduced from 61.7 points at baseline to 18.7 points at 41 months' follow-up. For more details, refer to the 'Sources of evidence' section.
- 2.3.3 The Specialist Advisers noted that the procedures may be undertaken concurrently with disc decompression or discectomy. It is therefore difficult to determine what clinical benefit is derived from the implants themselves.

2.4 Safety

- 2.4.1 In one case study, 3% (7/280) of screws implanted as part of non-rigid stabilisation systems loosened during 38 months of follow-up; 13% (11/83) of patients required further surgery, with eight of them having the implant removed. In another series, 10% (3/31) of patients had malpositioned screws and 3% (1/31) had loosening of a screw. In the same study there was one case each of pleural effusion, cardiac insufficiency and dural tear.
- 2.4.2 In a retrospective case series, dural tears occurred in 4% (2/51) of patients. The re-operation rate was 22% (11/51).

- 2.4.3 In a comparative study, additional surgery was required for adjacent level disc lesion, disc herniation or spinal stenosis by 6% (1/18) of patients who had ligament implantation and 19% of patients who had fusion. For more details, refer to the 'Sources of evidence' section.
- 2.4.4 The Specialist Advisers noted that the reported adverse events include: malpositioned or broken screws leading to nerve root damage; infection; cerebrospinal fluid leak; failure of the bone/implant interface; and failure to control pain. The theoretical risks with the techniques include: device failure (particularly long term); increased lordosis; and root damage caused by loose or misaligned screws.

3 Further information

- 3.1 The Institute has issued guidance on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication (www.nice.org.uk/IPG165).
- Andrew Dillon
Chief Executive
June 2006

Understanding NICE guidance

NICE has produced information describing its guidance on this procedure for patients and their carers. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG183publicinfo

Sources of evidence

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

'Interventional procedure overview of non-rigid stabilisation techniques for the treatment of low back pain', July 2005.

Available from: www.nice.org.uk/ip306overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1070. *Information for the public* can be obtained by quoting reference number N1071.

The distribution list for this guidance is available at www.nice.org.uk/IPG183distributionlist

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