# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of non-rigid stabilisation techniques for the treatment of low back pain

Chronic low back pain is most often the result of normal wear and tear (degenerative change) which affects most people during their middle years, causing loss of height of the spinal discs and arthritis of the spinal joints. Non-rigid stabilisation (otherwise known as flexible or dynamic stabilisation) of the lumbar spine is intended to improve chronic low back pain by reducing painful movement without rigidly fusing the spine.

## Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This overview was prepared in October 2009.

## Procedure name

- Non-rigid stabilisation techniques for the treatment of low back pain.

## Specialty societies

- British Association of Spinal Surgeons.
- British Orthopaedic Association.
- Society of British Neurological Surgeons.

# Description

## *Indications and current treatment*

Chronic low back pain is most often the result of normal wear and tear (degenerative change) which affects most people with increasing age. Such degenerative changes may include shrinkage of intravertebral discs and facet joint arthritis leading to back pain.

Acute low back pain is usually treated by a combination of pharmacological treatments (analgesia and muscle relaxants), physical therapies (which may include posture training), and lifestyle advice (such as weight loss).

For patients with severe, life-limiting chronic low back pain refractory to conservative management, spinal fusion surgery may be appropriate to immobilise the spinal segments thought to be the source of pain. An alternative approach is the insertion of artificial intravertebral disc(s).

## *What the procedure involves*

Non-rigid (otherwise known as flexible or dynamic) stabilisation of the lumbar spine is a surgical procedure that aims to support and partially restrict the movement of spinal segments. The procedure also aims to minimise abnormal loading in adjacent segments associated with complete vertebral body fusion.

With the patient under general or epidural anaesthesia, the spine is accessed using a posterior approach via a midline incision, or by minimal access techniques. Adjacent vertebrae are linked by a non-rigid connector system (usually pedicle screws and an artificial ligament or flexible rod) to restrict painful intervertebral movements More than one segment may be stabilised non-rigidly at the same time. The procedure may be done in combination with laminectomy and/or discectomy where judged appropriate. Several different systems are available and many more are being developed.

## *Instruments used to assess efficacy*

The Oswestry Disability Index (ODI) assesses 10 items: pain intensity, personal care, lifting, walking/walking aids, sitting, standing, sleeping, sex life, social life and travelling. Scores are from 0 to 100% with higher scores meaning greater disability.

Pain can also be measured on a visual analogue scale (VAS). Scores range from 1 to 10 or 0 to 100: low scores indicate less pain.

The Prolo scale measures functional and economic status. There are 5 categories for functional status (ranging from ‘total incapacity’ to ‘all previous sports and activities resumed’) and 5 for economic status (ranging from ‘complete invalid’ to ‘working with no restrictions of any kind’).

# Literature review

## *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to non-rigid stabilisation techniques for the treatment of low back pain. Searches were conducted of the following databases, covering the period from their commencement to 13 October 2009: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

| Characteristic | Criteria |
|---|---|
| Publication type | Clinical studies were included. Emphasis was placed on identifying good quality studies.<br>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.<br>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. |
| Patient | Patients with low back pain. |
| Intervention/test | Non-rigid stabilisation techniques. |
| Outcome | Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy. |
| Language | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base. |

## *List of studies included in the overview*

This overview is based on 978 patients from 7 non-randomised comparative studies[1,2,3,4,5,6,7] and 3 case series[2,8,9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

## Table 2 Summary of key efficacy and safety findings on non-rigid stabilisation techniques for the treatment of low back pain

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kanayama M (2009)[1]<br><br>Non-randomised comparative study<br><br>Japan<br>Recruitment period: 1997 - 2004<br><br>Study population: patients with low back pain and sciatic symptoms and who had no improvement after non-operative treatment.<br><br>n = 218 (78 PLIF vs 75 PLF vs 65 Graf ligamentoplasty)<br><br>Age: PLIF: 60 years (mean), PLF: 64 years (mean) and Graf ligamentoplasty: 63 years (mean)<br>Sex: PLIF: 48.7% (38/78) male, PLF: 41.3% (31/75) male and Graf ligamentoplasty: 33.8% (22/65) male<br><br>Patient selection criteria: patients with degenerative scoliosis were excluded.<br><br>Technique: PLIF (using Brantigan carbon-fibre I/F cages) vs PLF vs Graf ligamentoplasty (using Graf artificial ligament stabilization system)<br><br>Follow-up: PLIF: 37 months (mean), PLF: 45 months (mean) and Graf ligamentoplasty: 41 months (mean)<br><br>Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 218 (78 PLIF vs 75 PLF vs 65 Graf ligamentoplasty)<br><br>Results at final follow-up:<br><br>
<table>
<tr><th></th><th>Prevalence of adjacent segment disease</th><th>Additional surgery required for adjacent segment disease</th></tr>
<tr><td>PLIF</td><td>14.1% (11/78)</td><td>7.6% (6/78)</td></tr>
<tr><td>PLF</td><td>13.3% (10/75)</td><td>6.6% (5/75)</td></tr>
<tr><td>Graf ligamentoplasty</td><td>9.2% (6/65)</td><td>1.5% (1/65)</td></tr>
</table>
No significant differences between groups<br><br>Types of subsequent procedures:<br>PLIF group: 66.6% (4/6) had supplemental fusion. Paper does not state what type of procedure the other 2 patients received.<br>PLF group: all 5 had decompression procedures<br>Graf ligamentoplasty group: type of procedure not stated.<br><br>
<table>
<tr><th></th><th>Mean postoperative segmental lordosis</th><th>Kyphotic fusion / stabilisation</th></tr>
<tr><td>PLIF</td><td>11.2°</td><td>1.4% (1/78)</td></tr>
<tr><td>PLF</td><td>14.6°*</td><td>1.3% (1/75)</td></tr>
<tr><td>Graf ligamentoplasty</td><td>14.5°*</td><td>0</td></tr>
</table>
*P < 0.05 in comparison to PLIF group</td>
<td>Not reported.</td>
<td>Follow-up issues:<br>• An additional 6 patients (2 in each group) were lost to follow-up at 2 years and not included in the results.<br><br>Study design issues:<br>• Single centre study.<br>• Radiographic assessment to confirm segmental lordosis.<br><br>Study population issues:<br>• Diagnosis at baseline: degenerative spondylolisthesis = 82.6% (185/224), disc herniation (13/224) = 5.8, isthmic spondylolisthesis: 4.5% (10/224), spinal stenosis: 2.2% (5/224) and foraminal stenosis: 2.2% (5/224).</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kim Y-S (2007)[2]<br><br>Non-randomised comparative study<br><br>Korea<br><br>Recruitment period: 2005-2006<br><br>Study population: patients with symptoms of disabling low back pain with or without leg pain with no improvement after 6 weeks of conservative treatment<br><br>n = 103 (46 vs 57)<br><br>Age: 49.9 years (mean)<br>Sex: dynamic group: 28.3% (13/46) male; rigid group: 21.1% (12/57) male<br><br>Patient selection criteria: patients with active infection excluded from use of BioFlex system.<br><br>Technique: dynamic stabilisation (BioFlex system after wide laminectomy with or without discectomy, or 360° fixation with an interbody cage and BioFlex device at the main diseased segment and BioFlex stabilisation at the adjacent transitional segments) vs. rigid fixation (360° fixation with an interbody cage implanted for PLIF and BioFlex fixation at diseased segments only)<br><br>Follow-up: dynamic group: 9.3 months (mean); rigid group: 10.6 months (mean)<br><br>Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 103 (46 vs. 57)<br><br>Range of motion
<table>
<tr><td></td><td>Dynamic group*</td><td>Rigid group</td></tr>
<tr><td>ROM preoperatively</td><td>8.4±3.4°</td><td>6.5±3.2°</td></tr>
<tr><td>ROM postoperatively (timing unclear in the paper)</td><td>10.7±3.2°</td><td>10.5±4.6°</td></tr>
<tr><td>p value</td><td>0.001</td><td>0.001</td></tr>
</table>
* reported as 10.0±4.3° (pre-op) and 4.1±1.9° (postop), p = 0.001 in the text. IP analyst reported values in Table 4 of the paper.<br><br>VAS score for low back and leg pain
<table>
<tr><td></td><td colspan="2">Dynamic group</td><td colspan="2">Rigid group</td></tr>
<tr><td></td><td>Pre-op</td><td>Postop</td><td>Pre-op</td><td>Postop</td></tr>
<tr><td>Low back pain score</td><td>7.3±3.1</td><td>1.4±1.8</td><td>7.4±2.4</td><td>2.1±2.3</td></tr>
<tr><td>Leg pain score</td><td>7.4±2.6</td><td>1.3±1.6</td><td>7.5±1.6</td><td>1.4±2.1</td></tr>
</table>
No significant difference between groups<br><br>Oswestry Disability Index
<table>
<tr><td></td><td>Dynamic group</td><td>Rigid group</td></tr>
<tr><td>Preoperative score</td><td>35.2±6.4</td><td>37.8±5.7</td></tr>
<tr><td>Follow-up score</td><td>12.1±4.5</td><td>13.6±4.2</td></tr>
</table>
p values not reported for Oswestry Disability Index</td>
<td>Screw fracture: 1 patient at 3 months with no complaints. Loosening of screw housing cap: 1 patient at day 7, re-tightened and patient has no other problems. Unclear which arm of the study this complication occurred in.<br><br>One patient with degenerative spondylolisthesis in group 2 had a degenerative change in an adjacent segment at 1 year and had a further fusion procedure.</td>
<td>Follow-up issues:<br>• Only patients with >6-month follow-up included in the study.<br><br>Study design issues:<br>• Retrospective study<br><br>From the description of interventions used in the 2 groups, it is not clear whether some patients also had rigid spinal fusion.<br><br>Study population issues:<br>• Diagnosis at baseline: spondylytic spondylolisthesis = 46 patients, degenerative spondylolisthesis = 26 patients, degenerative spinal canal stenosis = 12 patients, chronic degenerated herniated lumbar disc = 9 patients, FBSS = 7 patients and trauma = 3 patients.</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Putzier M (2005)[3]<br><br>Non-randomised comparative study<br><br>Germany<br><br>Recruitment period: not reported<br><br>Study population: patients with symptomatic disc prolapse and initial segment degeneration.<br><br>n = 84 (35 vs 49)<br><br>Age: 37 years (mean)<br>Sex: 60.7% (51/84) male<br>Mean duration of symptoms prior to procedure: 7 weeks<br><br>Patient selection criteria: symptoms equivalent to a radicular syndrome. Patients excluded if they had epidural adhesions and/or periradicular fibrosis on MRI following previous nucleotomy, marked facet joint arthritis, spinal stenosis, spondylolisthesis, lumbar scoliosis >10°, osteoporosis, malignant tumours, body mass index >30kg/m$^2$ or drug/alcohol abuse.<br><br>Technique: nucleotomy of the lumbar spine and non-rigid stabilisation (using Dynesys implant) vs. nucleotomy only<br><br>Follow-up: 34 months (mean)<br><br>Conflict of interest/source of funding: none</td>
<td>Clinical symptoms<br>Proportion of patients who had complete remission of neurological symptoms at final follow-up:<br>Dynesys + nucleotomy group: 74.3% (26/35)<br>Nucleotomy only group: 71.4% (35/39) (p = NS)<br><br>Oswestry low back pain score improved significantly from baseline to 3-month assessment in both groups (p<0.05), although there was no significant difference between groups.<br><br>At final follow-up there was a significant improvement in pain on VAS in the nucleotomy group (p < 0.05) but not in the Dynesys + nucleotomy group.<br><br>Radiographic evaluation (unclear if 3-month or final follow-up)
<table>
<tr><th></th><th>Dynesys + nucleotomy (n = 35)</th><th>Nucleotomy only (n = 49)</th></tr>
<tr><td>Progressive height reduction of the intervertebral space >20%</td><td>0%</td><td>10.2% (5/49)</td></tr>
<tr><td>Signs of progressive degeneration</td><td>0%</td><td>16.3% (8/49)</td></tr>
<tr><td>New appearance or progression of spondylarthrosis</td><td>0%</td><td>12.2% (6/49)</td></tr>
<tr><td>Re-prolapse at follow-up</td><td>0%</td><td>2% (1/49)</td></tr>
</table>
Patient satisfaction at follow-up<br>Overall: 89% (73/82) patients were very or considerably satisfied with the results of treatment; 6 of the unsatisfied patients were in the nucleotomy only group and 3 were in the Dynesys + nucleotomy group.</td>
<td>Intraoperative complications<br>Damage to the dura (closed immediately with a primary suture and fibrin glue):<br>Dynesys + nucleotomy group: 6% (2/35)<br>Nucleotomy only group: 6% (3/49)<br><br>Mean blood loss:<br>Dynesys + nucleotomy group: 190ml<br>Nucleotomy only group: 135ml (p = 0.05)<br><br>Postoperative complications<br>A superficial wound healing disorder was experienced by 1 patient in the Dynesys + nucleotomy group.<br><br>There were no implant-associated complications.<br><br>Radiological evaluation found no loosening, misalignment, or breakage of screws during follow-up.</td>
<td>Reported in Table 2 in original overview<br><br>Follow-up issues:<br>• No loss to follow-up at 3 months<br><br>Study design issues:<br>• Dynesys group data collected prospectively and compared to retrospective data on patients treated prior to the introduction of the device to the institution. The control group were matched for age and symptoms.<br>• Insertion of the Dynesys system required a 7-cm incision rather than a 4-cm incision for the minimally invasive nucleotomy.</td>
</tr>
</table>

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<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Hadlow SV (1998)[4]<br><br>Non-randomised comparative study<br><br>Australia<br><br>Recruitment period: 1992 - 1993<br><br>Study population: patients with low back pain<br><br>n = 83 (53 vs 30)<br><br>Age: Graf ligamentoplasty: 42 years (mean), Fusion: 46 years (mean)<br>Sex: Graf ligamentoplasty: 47% male; Fusion: 43% male<br><br>Patient selection criteria:<br><br>Technique: Graf ligamentoplasty vs. fusion<br><br>Follow-up: 31 months (mean)<br><br>Conflict of interest/source of funding: supported by Adelaide Bone and Joint Research Foundation</td>
<td>Number of patients analysed: 83 (53 vs 30)<br>Average segmental angular motion in Graf ligamentoplasty group: 4.3°.<br><br>Low back outcome score (higher scores are better) at 1 year:<br>Graf ligamentoplasty: 27.6<br>Fusion: 35.3 (p = 0.02). This finding was not significant at 2 years, p = 0.34.<br><br>Procedures additional to index operation:<br>Graf ligamentoplasty: 2 metal removal procedures, 2 disectomies and 18 root decompressions.<br>Fusion: 1 metal removal, 1 discectomy and 14 root decompressions (p = 0.27).<br><br>Average segmental angular motion in Graf ligamentoplasty group (n=20): 4.3°.<br><br>Re-operation rates (total number of procedures)
<table>
<tr><th></th><th>Graf ligamentoplasty</th><th>Fusion</th><th>p value</th></tr>
<tr><td>0 to 6 weeks</td><td>13</td><td>10</td><td>-</td></tr>
<tr><td>1st year</td><td>55</td><td>37</td><td>0.11</td></tr>
<tr><td>2nd year</td><td>72</td><td>43</td><td>0.01</td></tr>
</table>
Indications for reoperation in the Graf ligamentoplasty group (number of patients):
<table>
<tr><th></th><th>0 to 6 weeks</th><th>1st year</th><th>2nd year</th></tr>
<tr><td>Nerve root compromise</td><td>7</td><td>4</td><td>1</td></tr>
<tr><td>Continuing back pain requiring implant removal and further stabilisation</td><td>-</td><td>11</td><td>13</td></tr>
<tr><td>Replacement of loose bands</td><td>-</td><td>1</td><td>-</td></tr>
<tr><td>Implantation of analgesic infusion pump</td><td>-</td><td>1</td><td>-</td></tr>
</table>
</td>
<td>Graf ligamentoplasty group:<br>Deep infection: 1 patient required surgical debridement after early re-operation to reposition a malpositioned pedicle screw.<br><br>Fusion group:<br>Superficial wound infection (1 patient treated with oral antibiotics.<br><br>Note number of re-operation events for ‘nerve root compromise’ reported alongside other re-operation causes in the ‘efficacy’ column.</td>
<td>Follow-up issues:<br>• 2-year follow-up low back outcome score: 85% patients in the Graf ligamentoplasty group and 90% of patients in the fusion group.<br><br>Study design issues:<br>• Described as a retrospective case-control study by the authors.<br>• Single surgeon’s experience reported.<br>• Patient chose type of operation (all patients were offered both procedures).<br>• Independent assessors reviewed patients at 1 and 2 years.<br>• Low back outcome scores: excellent = 66– 75, good = 5–65, fair = 30–49 and poor = less than 30.</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kanayama M (2001)[5]<br><br>Non-randomised comparative study<br><br>Japan<br><br>Recruitment period: not reported<br><br>Study population: patients with spondylolisthesis or flexion instability requiring stabilisation<br><br>n = 45 (18 vs. 27)<br><br>Age: 57 years (mean)<br>Sex: 48.9% (22/45) male<br><br>Patient selection criteria: Graf group: only patients with mild degenerative spondylolisthesis; flexion instability; no or minimal disc space narrowing; or coronal facet articulation.<br><br>Technique: Graf ligamentoplasty (using titanium pedicle screws and braided polyester bands) vs. fusion (using bone graft and pedicle screw instrumentation)<br><br>Follow up: Graf group: 71 months (mean), fusion group: 75 months (mean)<br><br>Conflict of interest/source of funding: not reported</td>
<td>Radiographic evaluation<br>Assessment of lumbar sagittal alignment and MRI of adjacent discs with deterioration determined by a decrease in signal intensity at follow-up compared with baseline
<table>
<tr><th></th><th>Graf</th><th>Fusion</th><th>p value</th></tr>
<tr><td>Global lumbar lordosis</td><td>36.1<br>± 16.0 °</td><td>40.6<br>± 15 °</td><td>NS</td></tr>
<tr><td>Level 4–5 Range of movement</td><td>4.3<br>± 3.3°</td><td>0.4<br>± 1.4°</td><td>< 0.05</td></tr>
</table>
The rate of adjacent disc deterioration by X-ray assessment was statistically higher with fusion (~36%) than with the Graf ligamentoplasty (~7%; p < 0.05) at the L2–3 level (numbers derived from figures presented). However, this difference was not statistically significant for all other levels.<br><br>MRI evaluation of adjacent discs found no significant difference between the groups in the incidence of deterioration from baseline<br><br>Clinical evaluation<br>Additional surgery was required for adjacent-level disc lesion, disc herniation or spinal stenosis in 5.6% (1/18) of cases in the Graf group and 18.5% (5/27) of the fusion group at 5-year follow-up</td>
<td>Not reported</td>
<td>Reported in Table 2 in original overview<br><br>Follow-up issues:<br><br>• Follow-up rate of patients available for analysis was 64% in both groups. Not stated how others lost to follow-up.<br><br>Study design issues:<br>• Radiological evaluation undertaken by an independent assessor.<br>• Patients treated on basis of clinical presentation, and therefore were not comparable at baseline. The indications for surgery were not the same, therefore the groups were not matched in some clinical parameters; however, the adjacent disc status was comparable between the two.<br><br>Study population issues:<br>• Diagnosis: degenerative spondylolisthesis = 29 patients, spinal stenosis = 6 patients, disc herniations = 10 patients, isthmic olisthesis = 4 patients and recurrent disc herniation = 4 patients.<br>• Fusion group: 92.6% achieved complete fusion.</td>
</tr>
</table>

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<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ozer AF (2010)[6]<br><br>Non-randomised comparative study<br><br>Turkey<br><br>Recruitment period: not reported<br><br>Study population: patients with degenerative disc disease<br><br>n = 41 (19 vs. 22)<br><br>Age: dynamic group: 57.4 years (mean), fusion group: 54.5 years (mean)<br>Sex: dynamic group:26.3% (5/19) male, fusion group: 45.5% (10/22) male<br><br>Patient selection criteria: patients with disc degeneration with degenerative spondylolisthesis, failed nucleoplasty and recurrent disc herniation were excluded from the study.<br><br>Technique: lumbar pedicular dynamic stabilisation system vs. fusion. Both procedures used fluoroscopic guidance and all patients were stabilised at 1 lumbar level.<br><br>Follow up: 2 years<br><br>Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 41 (19 vs 22)<br><br>
<table>
<tr><td></td><td colspan="2">Dynamic group (n = 19)</td><td colspan="2">Fusion group (n = 22)</td></tr>
<tr><td></td><td>Pre-operative score</td><td>24 months</td><td>Pre-operative score</td><td>24 months</td></tr>
<tr><td>ODI</td><td>64.5</td><td>7.4</td><td>62</td><td>8.6</td></tr>
<tr><td>VAS</td><td>6.7</td><td>1.1</td><td>7.5*</td><td>1</td></tr>
</table>
*p = 0.045 compared to dynamic group pre-operative score.<br>
The VAS and ODI scores decreased significantly at 24 months in both groups (p < 0.002).<br><br>
<table>
<tr><td></td><td colspan="2">Dynamic group (n = 19)</td><td colspan="2">Fusion group (n = 22)</td></tr>
<tr><td></td><td>Pre-operative</td><td>24 months</td><td>Pre-operative</td><td>24 months</td></tr>
<tr><td>Lumbar lordosis angle</td><td>45.9±15.1</td><td>45.8±13.0</td><td>51.2±10.9</td><td>46.1±10.2*</td></tr>
<tr><td>Segmental lordosis angle</td><td>11. ±5.5</td><td>9.3±4.4</td><td>10.9±5.0</td><td>9.9±3.0</td></tr>
</table>
*p = 0.038 compared to preoperative angle.<br><br>
<u>Mean duration of hospital stay:</u><br>
Dynamic group: 6.2 days<br>
Fusion group: 7.9 days (p = 0.26)</td>
<td>Dynamic group:<br>Loosening of caudal screws: 2 patients (treatment not reported).<br><br>Fusion group:<br>Pseudoarthrosis requiring re-operation: 2 patients.<br>Broken screws(did not require further operation): 2 patients.</td>
<td>Follow-up issues:<br>• Completeness of follow-up is not reported.<br><br>Study design issues:<br>• Unclear if single centre/single surgeon study.<br>• Patient chose type of operation (all patients were offered both procedures).</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Cakir B (2009)[7]<br><br>Non-randomised comparative study<br><br>Germany<br><br>Recruitment period: not reported<br><br>Study population: patients with low back pain and claudication due to degenerative instability at L4-L5 with concomitant spinal stenosis<br><br>n = 26 (11 vs. 15)<br><br>Age: Dynesys group: 57.1 years (mean); fusion group: 57.9 years (mean)<br>Sex: 42.3% (11/26) male<br><br>Patient selection criteria: all patients had to have 6–12 months of intensive conservative therapy. Patients had to have regular lumbar anatomy. Patients requiring surgery for trauma, infection or tumour were excluded. Dynesys group: patients excluded if they had instability of more than 5mm or disc height less than 5mm.<br><br>Technique: Dynesys posterior dynamic stabilisation vs. decompression and fusion (using Krypton, angle-stable internal fixator and autologous bone from iliac crest)<br><br>Follow-up: Dynesys group: 37.5 months (mean); fusion group: 45.3 months (mean)<br><br>Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 26 (11 vs. 15)<br><br>Range of motion (an increase in motion is defined as a change of more than 3.2°)
<table>
<tr><th></th><th colspan="3">Dynamic group</th><th colspan="3">Rigid group</th></tr>
<tr><th></th><th>baseline</th><th>6 weeks</th><th>p value</th><th>Baseline</th><th>6 weeks</th><th>p value</th></tr>
<tr><td>Mean lumbar spine (L2-S1) ROM</td><td>14.4±9.7°</td><td>18.3±8.4</td><td>0.05</td><td>23.6±16.2°</td><td>12.7±7.1</td><td>0.02</td></tr>
<tr><td>Mean index level (L4-L5) ROM*</td><td>4.0±4.0°</td><td>4.1±3.7°</td><td>0.72</td><td>6.3±5.6°</td><td>1.6±1.2°</td><td>0.001</td></tr>
<tr><td>Mean cranial adjacent segment (L3-L4) ROM†</td><td>3.3±3.4°</td><td>3.9±2.5°</td><td>0.72</td><td>7.1±7.0°</td><td>4.2±4.2°</td><td>0.35</td></tr>
<tr><td>Mean caudal adjacent segment (L5-S1) ROM†</td><td>5.4±4.2°</td><td>5.0±3.9°</td><td>0.79</td><td>5.2±4.1°</td><td>5.1±4.7°</td><td>0.91</td></tr>
</table>
*Authors state “a significant difference was noted between the groups of fused and dynamically instrumented patients with a decrease in segmental ROM in most cases of the fusion group” (no p-value reported)<br>† no significant difference between dynamic and rigid groups<br><br>Proportion of patients with preserved motion (defined as ROM >3.2°)
<table>
<tr><th></th><th colspan="3">Dynamic group</th><th colspan="3">Rigid group</th></tr>
<tr><th></th><th>baseline</th><th>6 weeks</th><th>p value</th><th>Baseline</th><th>6 weeks</th><th>p value</th></tr>
<tr><td>Index level (L4-L5)</td><td>45.5% (5/11)</td><td>27.3% (3/11)</td><td>0.66</td><td>66.7% (10/15)</td><td>13.3% (2/15)</td><td><0.01</td></tr>
<tr><td>Cranial adjacent segment (L3-L4)</td><td>27.3% (3/11)</td><td>54.5% (6/11)</td><td>0.39</td><td>46.7% (7/15)</td><td>53.3% (8/15)</td><td>1.0</td></tr>
<tr><td>Caudal adjacent segment (L5-S1)</td><td>63.6% (7/11)</td><td>54.5% (6/11)</td><td>1.0</td><td>66.7% (10/15)</td><td>60% (9/15)</td><td>1.0</td></tr>
</table>
</td>
<td>Not reported</td>
<td>Follow-up issues:<br>• No loss to follow-up at 6 weeks<br><br>Study design issues:<br>• Retrospective study</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kim Y-S (2007)[2]<br><br>Case series<br><br>Korea<br><br>Recruitment period: 2004–2005<br><br>Study population: patients with degenerative spinal diseases or osteoporotic compression fractures<br><br>n = 194<br><br>Age: 60.8 years (mean)<br>Sex: 35.6% (69/194) male<br><br>Patient selection criteria: degenerative stenosis with or without disc herniation, compression fractures with kyphosis, degenerative spondylolisthesis, injury of posterior ligamentous structures.<br><br>Technique: posterior dynamic stabilisation using Nitinol shape memory loop<br><br>Follow-up: 1 year<br><br>Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 194<br><br>Postoperative success at 1-year follow-up (Prolo scale)<br>Excellent: 28.4% (55/194)<br>Good: 62.4% (121/194)<br>Fair: 6.2% (12/194)<br>Poor: 3.1% (6/194)<br><br>Range of motion
<table>
<tr><th></th><th>No. of segments</th><th>Baseline ROM</th><th>1 year ROM</th><th>p value</th></tr>
<tr><td>Within looped segments, including PLIF</td><td>341</td><td>5.26±3.38°</td><td>2.18±3.39°</td><td>0.001</td></tr>
<tr><td>Within looped segments, excluding PLIF</td><td>145</td><td>5.04±3.12°</td><td>5.13±3.46°</td><td>0.807</td></tr>
<tr><td>One adjacent level beyond looped segment</td><td>272</td><td>4.61±2.92°</td><td>4.9±3.36°</td><td>0.215</td></tr>
</table>
Change in kyphosis
<table>
<tr><th></th><th>Baseline angle</th><th>1 year angle</th><th>p value</th></tr>
<tr><td>Mean kyphotic angle</td><td>23.96±11.7°</td><td>16.25±12.34°</td><td>0.007</td></tr>
</table>
</td>
<td>Hardware failures: 2.1% (4/194). Two memory loop fractures and 2 pullouts of memory loop.<br><br>Timing and treatment of complications is not reported.</td>
<td>Follow-up issues:<br>• Loss to follow-up not reported<br><br>Study design issues:<br>• Retrospective study<br>• Prolo scale measures functional and economic status.<br><br>Other issues:<br>• Reported in same Kim paper as the non-randomised comparative study in the first table.</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Welch WC (2007)[8]<br><br>Case series<br><br>USA<br><br>Recruitment period: 2003 – 2006<br>Study population: patients with degenerative spondylolisthesis or retrolisthesis (Grade I), lateral or central spinal stenosis thought to require decompression and fusion.<br><br>n= 101<br><br>Age: 56.3 years (mean)<br>Sex: 47.5% (48/101) male<br>Previous lumbar surgery: 42.6% (43/101) patients<br><br>Patient selection criteria: patients predominantly had leg pain (≥40 on VAS) rather than back pain and had at least moderate disability (Oswestry Disability Index ≥30%) and unresponsive to conservative treatment for at least 3 months. Patients excluded if under 20 years or over 80 years, had body mass index >40, previous fusion or total facetectomy performed, required surgery for trauma, had osteoporosis, malignancy or active infection.<br><br>Technique: Dynesys implant. A pedicle screw system for mobile stabilisation, consisting of titanium alloy screws connected by an elastic synthetic compound. Surgery performed using a mid-line approach and decompression was performed before insertion of the implant. The correct position of the implant was confirmed by fluoroscopy<br><br>Follow-up: 1 year<br>Conflict of interest/source of funding: several authors employed by /are consultants for manufacturer</td>
<td>Number of patients analysed: 101<br><br>
<table>
<tr><th></th><th>Baseline (n = 101)</th><th>Follow-up (n = 80)</th><th>p value</th></tr>
<tr><td>Lower back pain (mean score)</td><td>54</td><td>29.4</td><td>< 0.01</td></tr>
<tr><td>Leg pain (mean score)</td><td>80.3</td><td>25.6</td><td>< 0.01</td></tr>
<tr><td>Oswestry Disability Index (mean score)</td><td>55.6%</td><td>26.3%</td><td>< 0.01</td></tr>
<tr><td>Short Form-12 mental component score</td><td>41.6</td><td>49.4</td><td><0.01</td></tr>
<tr><td>Short Form-12 physical component score</td><td>27.3</td><td>40.3</td><td><0.01</td></tr>
<tr><td>Patient satisfaction</td><td>-</td><td>79</td><td>-</td></tr>
<tr><td>Willingness to recommend the operation to friend / relative</td><td>-</td><td>73</td><td>-</td></tr>
</table>
</td>
<td>Intraoperative complications:<br>Overall intraoperative complications: 15.8% (16/101)<br>• Dural tears: 11.9% (12/101). 11 repaired intraoperatively and 1 discovered postoperatively and resolved with bed rest. One of the tears repaired intraoperatively continued to leak and additional surgery was required to close the lesion.<br>• Excessive blood loss requiring transfusion:2% (2/101)<br>• Allergic reaction to anaesthesia: 1 patient (procedure aborted and rescheduled)<br>• Fractured pedicle during screw insertion: 1 patient (pedicle screw not placed and a hemilaminectomy completed)<br><br>At follow-up:<br>During the follow-up period 15% (15/101) of patients required 18 further procedures.<br>• 3 of the procedures were the result of immediate postoperative complications (1 had a tracheostomy due to respiratory arrest, 1 had debridement for wound dehiscence, and 1 had a cerebrospinal fluid leak requiring sutures and sealing with fibrinogenic material).<br>• 10 of the procedures were revision surgery for increased back pain, radiculopathy or increased instability. Procedures included decompression, extension of segmental fixation and removal of a synovial facet cyst. Removal of Dynesys implant required in 3 of these procedures (2 due to radicular symptoms and 1 due to back pain).<br>• 5 of these procedures were unrelated to the spine or the initial procedure.</td>
<td>Follow-up issues:<br>• 20.8% (21/101) patients lost to follow-up at 1 year.<br><br>Study design issues:<br>• Prospective multicentre study (6 sites).<br>• Preliminary clinical results for Food and Drug Administration trial.<br>• Pain, measured on a visual analogue scale (0–100), low scores indicates less pain.<br>• Oswestry Disability Index (0–100% scale), low scores indicate less disability.<br>• Patient satisfaction and willingness rated on VAS from 0–100 (higher score are better).<br><br>Study population issues:<br>• Mean body mass index: 28.8<br>• Average duration of symptoms before procedure: 5.3 years<br>• Baseline primary diagnosis: lateral stenosis = 40 patients, central stenosis = 26 patients, spondylolisthesis =20 patients, retrolisthesis = 3 patients, other = 4 patients.</td>
</tr>
</table>

Abbreviations used: FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; NS, not significant; PLF, posterolateral lumbar fusion; PLIF, posterior lumbar interbody fusion; ROM, range of motion; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Stoll TM (2002)[9]<br><br>Case series<br><br>Switzerland<br><br>Recruitment period: not reported<br><br>Study population: patients with unstable segmental conditions, mainly combined with spinal stenosis<br><br>n = 83<br><br>Age: 58.2 years (mean)<br>Sex: 41% (34/83) male<br>Previous lumbar surgery: 36% (30/83) patients<br><br>Patient selection criteria: neurogenic, radicular pain or chronic lower back pain resistant to conservative treatment, presenting with some form of instability<br><br>Technique: Dynesys implant. A pedicle screw system for mobile stabilisation, consisting of titanium alloy screws connected by an elastic synthetic compound. Surgery performed using a midline approach with the pedicle screw positioned at the Magerl site. Decompression was performed where indicated. Postoperative bracing applied only in exceptional cases.<br><br>Follow-up: 38.1 months (mean)<br>Conflict of interest/source of funding: not reported</td>
<td>Functional status<br>Patients improved in functional status with 47.9% (35/73) reporting total incapacity at baseline and only 2.7% (2/73) remaining in that classification postoperatively<br><br>Pain and disability scores
<table>
<tr><th></th><th>Base-line</th><th>Follow-up</th><th>p value</th></tr>
<tr><td>Low back pain (mean score)</td><td>7.4 ± 2.6</td><td>3.1 ± 2.3</td><td>< 0.01</td></tr>
<tr><td>Leg pain (mean score)</td><td>6.9 ± 3.0</td><td>2.4 ± 2.1</td><td>< 0.01</td></tr>
<tr><td>Oswestry Disability Index (mean score)</td><td>55.4% ± 19.5%.</td><td>22.9% ± 19.3%</td><td>< 0.01</td></tr>
</table>
No patients were in the highest category (‘all previous sports and social activities’) of the Prolo functional status scale at baseline; after the procedure, there were 13.7% (10/73).<br><br>Economic status was also improved although a significant proportion of patients were retired at the time of surgery, thus limiting the suitability of this scale as a measure of efficacy.</td>
<td>Dural lesions: 2.4% (2/83). One patient had revision surgery; superficial infection: 1 patient; paresis: 1 patient (reoperated at 1 month – same patient died of non-Hodgkin lymphoma);<br>hypesthesia: 1 patient; seroma: 1 patient (surgically drained); scar neuroma: 1 patient (excised); cardiovascular complication: 1 patient ; thromboembolism: 1 patient<br>Device durability<br>Of the 83 operations undertaken, 2 had screw misplacement (1 patient reoperated on at 2 weeks because of root compression signs, symptoms resolved after reoperation); 7 cases of screw loosening (confirmed by X-ray) were reported from 280 screws used (3.6%). Authors report that screw loosening rates seem to be similar to those seen with rigid pedicle instrumentation<br>Later additional surgery<br>During the follow-up period, 13% (11/83) of patients required 13 further procedures.<br>• 8 had a complete implant removal (3 of these at 17.6, 18.8 and 39.7 months for unresolved persistent pain and 2 of these required fusion; 4 implant removals at 5.8, 9.1, 15 and 17.6 months had fusion).<br>• 2 patients required extension of the Dynesys implant to adjacent sections for additional stenosis at 14.5 and 20.8 months.<br>• 2 adjacent section decompressions were undertaken at 11.3 and 24.7 months in 1 patient who later had implant removed and fusion at 29.6 months.<br>• A laminectomy of the index segment was undertaken in 1 patient at 22 months.</td>
<td>Reported in Table 2 in original overview<br>Follow-up issues:<br>• 88% (73/83) patients available for follow-up (2 patients died, and 8 patients had implant removed).<br>Study design issues:<br>• Not stated that any efficacy symptom assessments have been validated for this condition.<br>• Assessment at follow-up performed by independent examiners.<br>• Pain, measured on a visual analogue scale (1–10), low scores indicates less pain.<br>• Oswestry Disability Index (0–100% scale), low scores indicate less disability.<br>Study population issues:<br>• 60.2% (50/83) patients with spinal stenosis at baseline. Specific results for patients with spinal stenosis not reported separately, efficacy results for different indications might be expected to vary but safety findings should be consistent across indications.<br>Other issues:<br>• This was the first series of patients and a learning curve in operative technique can be expected.<br>• Comparison of evidence of overload sequelae from fusion studies is not possible due to differing study parameters.</td>
</tr>
</table>

## *Efficacy*

### Reduced requirement for further spinal surgery due to protection against degeneration in adjacent segment

A non-randomised comparative study of 218 patients (78 PLIF vs 75 PLF vs 65 Graf ligamentoplasty) reported 6 patients in the PLIF group, 5 patients in the PLF group and 1 patient in the Graf ligamentoplasty group required re-operation for adjacent segment disease at follow-up of 37–45 months (no significant difference between groups)[1].

A non-randomised comparative study of 103 patients (46 dynamic stabilisation vs. 57 rigid stabilisation) reported 1 patient in the rigid group with degenerative spondylolisthesis who required a fusion at 1-year follow-up after developing degenerative change in an adjacent segment[2].

A non-randomised comparative study of 45 patients (18 dynamic stabilisation vs 27 fusion) reported that additional surgery was required for adjacent-level disc lesion disc herniation or spinal stenosis in 1 patient in the dynamic stabilisation group and 5 patients in the fusion group at mean follow-ups of 71 months and 75 months respectively[5].

A case series of 83 patients reported 2 patients requiring extension of the implant to adjacent sections for additional stenosis at 14.5 and 20.8 months; 2 adjacent section decompressions were undertaken at 11.3 and 24.7 months in 1 patient who later had implant removed and fusion at 29.6 months; and a laminectomy of the index segment was undertaken in 1 patient at 22 months[9].

### *Objectively measured outcomes*

### Range of motion (ROM)

A non-randomised comparative study of 26 patients (11 dynamic stabilisation vs. 15 rigid stabilisation) reported significant increase in the mean lumbar spine ROM from 14.4° at baseline to 18.3° at 6-week follow-up ($p = 0.05$). The study also showed significant decrease in mean lumbar spine ROM in the rigid stabilisation group from 23.6° at baseline to 12.7° at 6-week follow-up ($p = 0.02$)[7].

A case series of 194 patients reported a significant decrease in ROM within looped segments from 5.26° at baseline to 2.18° at 1-year follow-up ($p = 0.001$)[2].

### Adjacent segment disc deterioration

A non-randomised comparative study of 45 patients (18 dynamic stabilisation vs. 27 fusion) reported a rate of adjacent-segment disc deterioration at the L2–L3 level confirmed by X-ray in 36% of the fusion group and 7% in the dynamic

stabilisation group at mean follow-up of 75 months and 71 months respectively ($p<0.05$)[5].

***Patient reported outcomes***

**Back pain**

A non-randomised comparative study of 103 patients (46 dynamic stabilisation vs. 57 rigid stabilisation) reported improvement in back pain following both procedures measured using a visual analogue scale (VAS) from 0–10 (higher score indicates greater pain). The dynamic group's mean back pain score of 7.3 pre-operatively decreased to 1.4 at mean follow-up of 9.3 months compared with an improvement in the rigid group score from 7.4 to 2.1 at mean follow-up of 10.6 months (not significant)[2].

A non-randomised comparative study of 84 patients (35 dynamic stabilisation and nucleotomy vs. 49 nucleotomy only) reported significant improvement in back pain from baseline to 3-month assessment in both groups ($p < 0.05$), but there was no significant difference between groups[3].

A case series of 101 patients reported a significant decrease in mean low back pain score (measured on VAS from 0–100; higher scores indicate greater pain) from 54 at baseline to 29.4 at 1-year follow-up ($p < 0.01$)[8].

A case series of 83 patients reported significantly lower mean low back pain scores (measured on VAS from 0–10; higher score indicates greater pain) from 7.4 at baseline to 3.1 ($p < 0.01$) at mean follow-up of 38.1 months[9].

**Leg pain**

A non-randomised comparative study of 103 patients (46 dynamic stabilisation vs 57 rigid stabilisation) reported improvement in leg pain following both procedures measured using a VAS scale from 0–10. Mean back pain score in the dynamic group decreased from 7.3 pre-operatively to 1.4 at mean follow-up of 9.3 months; the rigid group score improved from 7.4 to 2.1 at mean follow-up of 10.6 months. There was no significant difference between the 2 groups[2].

A case series of 101 patients reported a significant decrease in mean leg pain score (measured on VAS from 0–100, higher scores indicate greater pain) from 80.3 at baseline to 25.6 at 1-year follow-up ($p < 0.01$)[8].

A case series of 83 patients reported significantly lower mean leg pain scores (measured on VAS from 0–10, higher score indicates greater pain) from 6.9 at baseline to 2.4 ($p < 0.01$) at mean follow-up of 38.1 months[9].

### Oswestry Disability Index

A non-randomised comparative study of 103 patients (46 dynamic stabilisation vs. 57 rigid stabilisation) reported improvement in the Oswestry Disability Index (ODI) following both procedures (scale 0–100%; higher scores indicate greater disability). The mean ODI score in the dynamic group improved from 35.2 pre-operatively to 12.1 at mean follow-up of 9.3 months; the rigid group ODI score improved from 37.8 pre-operatively to 13.6 at mean follow-up of 10.6 months (no p values reported)[2].

A non-randomised comparative study of 41 patients (19 dynamic stabilisation vs 22 fusion) reported significant improvement in ODI following both procedures. The mean ODI improved in the dynamic group from 64.5 pre-operatively to 7.4 at 24-month follow-up; the fusion group ODI improved from 62 pre-operatively to 8.6 at 24-month follow-up ($p < 0.002$ for both groups) [6].

Case series of 101 and 83 patients reported a significant decrease in mean ODI score from 56% at baseline to 26% at 1-year follow-up ($p < 0.01$)[8] and 55% at baseline to 23% at mean follow-up of 38.1 months[9].

### Quality of life

A case series of 101 patients reported a significant increase in Short Form-12 mental component score and physical component score from 41.6 at baseline to 49.4 at 1-year follow-up ($p < 0.01$) and 27.3 to 40.3 ($p < 0.01$) respectively[8].

### Patient satisfaction

A case series of 101 patients reported that 79% (63/80) of patients were satisfied at 1-year follow-up[8].

## *Safety*

### Dural damage

A non-randomised comparative study of 84 patients (35 dynamic stabilisation and nucleotomy vs. 49 nucleotomy only) reported damage to the dura that was closed immediately with sutures and fibrin glue in 2 patients in the dynamic stabilisation and nucleotomy group and in 3 patients in the nucleotomy only group[3].

A case series of 101 patients reported 12% (12/101) patients had dural tears. Eleven of the tears were repaired intraoperatively and 1 was discovered postoperatively. One of the tears repaired intraoperatively continued to leak and required further surgery to close the lesion[8].

A case series of 83 patients reported 2.4% (2/83) patients with dural lesions. One patient had revision surgery within 38.1 months mean follow-up[9].

**Re-operation required because of implant problems and other complications**

***Hardware loosening / fractures***

A non-randomised comparative study of 103 patients (46 dynamic stabilisation vs. 57 rigid stabilisation) reported 1 patient in the dynamic group with a screw fracture at 3 months and 1 patient with a loosened screw housing cap at day 7, which was retightened[2].

A non-randomised comparative study of 83 patients (53 Graf ligamentoplasty vs 30 fusion) reported that 1 patient in the Graf ligamentoplasty group required revision surgery to replace loose bands in the first year after the initial procedure[4].

The non-randomised comparative study of 41 patients reported 2 patients with loosening of caudal screws (treatment not reported) in the dynamic group and 2 patients with pseudoarthrosis requiring re-operation in the fusion group. An additional 2 patients in the fusion group had broken screws that did not require re-operation[6].

A case series of 194 patients reported 4 patients with hardware failures. Two patients had memory loop fractures and 2 patients had pullouts of the memory loop. The timing and treatment of the these complications is not reported[2].

A case series of 101 patients reported also reported 1 patient in whom the pedicle fractured during screw insertion. The pedicle screw was not placed and a hemilaminectomy was completed[8].

A case series of 83 patients reported 2 patients with screw misplacement (1 patient required revision surgery at 2 weeks because of root compression symptoms that resolved after the additional procedure), and 7 cases of screw loosening (confirmed by X-ray)[9].

***Immediate postoperative complications***

A case series of 101 patients reported 3 additional procedures for immediate postoperative complications (1 patient had a tracheostomy due to respiratory arrest, 1 patient had debridement for wound dehiscence, and 1 patient had a cerebrospinal fluid leak requiring sutures and sealing with fibrinogenic material)[8].

***Persistent pain / increased instability***

A non-randomised comparative study of 83 patients (53 Graf ligamentoplasty vs 30 fusion) reported 11 patients with continuing back pain requiring implant removal; and further stabilisation in the Graf ligamentoplasty group in the first year after the initial procedure and in 13 patients in the second year after the initial procedure. The same study also reported that 1 patient in the Graf ligamentoplasty group required re-operation to implant an analgesic infusion pump within the first year after the initial procedure and 12 patients in the same group required re-operation due to nerve root compromise (7 in the first 6 weeks, 4 within the first year and 1 in the second year after the initial procedure)[4].

A case series of 101 patients reported that 10 required revision surgery for increased back pain, radiculopathy or increased instability (the procedures included decompression, extension of segmental fixation and removal of a synovial facet cyst). Removal of the implant was required in 3 of these procedures (2 due to radicular symptoms and 1 due to back pain). Five of the procedures were unrelated to the spine or the initial procedure[8].

A case series of 83 patients reported that 8 patients had complete implant removal (3 were at 17.6, 18.8 and 39.7 months due to unresolved persistent pain, 2 required fusion; 4 were at 5.8, 9.1, 15 and 17.6 months and all required fusion)[9].

## *Validity and generalisability of the studies*

- No randomised controlled trial (RCT) evidence in the published literature.
- The studies include patients with different diagnosis at baseline including spondylolisthesis, stenosis and herniated discs.
- Different comparators are used in the non-randomised comparative studies including rigid stabilisation, nucleotomy and fusion.
- Several of the studies had substantial length of follow-up, which is useful; however, these studies report surgery typically performed in the mid-1990s and currently used surgical techniques or implants may have evolved to a point that somewhat minimises the relevance of this evidence.

## *Existing assessments of this procedure*

There were no published assessments from other organisations identified at the time of the literature search.

## *Related NICE guidance*

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

### Interventional procedures

- Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedures guidance 183 (2006). Available from www.nice.org.uk/guidance/IPG183 [current guidance]
- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedures guidance 306 (2009). Available from www.nice.org.uk/guidance/IPG306
- Percutaneous intradiscal electrothermal therapy for lower back pain. NICE interventional procedures guidance 319 (2009). Available from www.nice.org.uk/guidance/IPG319
- Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedures guidance 321 (2009). Available from www.nice.org.uk/guidance/IPG321
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedures guidance 300 (2009). Available from www.nice.org.uk/guidance/IPG300
- Percutaneous disc decompression using coblation for lower back pain. NICE interventional procedures guidance 173 (2006). Available from www.nice.org.uk/guidance/IPG173
- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedures guidance 141 (2005). Available from www.nice.org.uk/guidance/IPG141
- Endoscopic laser foraminoplasty. NICE interventional procedures guidance 31 (2003). Available from www.nice.org.uk/guidance/IPG31
- Percutaneous intradiscal radio frequency thermo coagulation for lower back pain. NICE interventional procedures guidance 83 (2004). Available from www.nice.org.uk/guidance/IPG83

- Percutaneous endoscopic laser thoracic discectomy. NICE interventional procedures guidance 61 (2004). Available from www.nice.org.uk/guidance/IPG61
- Laser lumbar discectomy. NICE interventional procedures guidance 27 (2003). Available from www.nice.org.uk/guidance/IPG27 (currently under review)

### Clinical guidelines

- Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009). Available from www.nice.org.uk/guidance/CG88

## Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Jeremy Fairbank (British Orthopaedic Association), Mr Jonathan R Johnson (British Association of Spinal Surgeons), Mr Philip Sell (Association of Spinal Surgeons and Mr Gordon Findlay (British Cervical Spine Society). The latter 2 specialists provided advice in 2005 and informed the Interventional Procedures team that their opinions remain unchanged.

- One Specialist Adviser has performed the procedure at least once over 10 years ago and states that it is used by some surgeons on a very limited evidence base. One Specialist Adviser has performed this procedure at least once and 2 others have never performed it.
- One Specialist Adviser stated that this is a novel procedure of uncertain safety and efficacy, one stated it is a minor variation and one stated it is established practice and no longer new. This Adviser stated that the procedure has been in use in the UK since 1999 with a peak in interest around 2005, but that there is less interest in the procedure now.
- The comparators are spinal fusion and intensive rehabilitation and/or physiotherapy (conservative treatment).

- Theoretical adverse events: paralysis, dural damage, vessel or visceral injury, adjacent level disc degeneration, increase in lordosis, nerve root entrapment, screw malpositioning leading to sciatica or nerve damage, weakness and numbness, screw breakage leading to construct failure, screw loosening and infection.
- Safety concerns: higher revision rate and that the procedure might make things worse.
- Efficacy outcomes: pain (measured on VAS), Oswestry Disability Index, reduction in adjacent segment disease, revision rates, return to work, patient satisfaction and quality of life (SF-36).
- One Adviser stated that the main concern is whether it works any better than conservative treatment. He reported that more recent papers (Schnake 2006, Wurgler-Hauri 2008, Kumar 2008 and Schaeren 2008) suggest the procedure is not as successful as originally perceived. These studies highlight high levels of revision surgery, screw loosening, breakage and misplacement, and adjacent segment degeneration.
- One Specialist Adviser indicated that there is no good evidence that the procedure is effective and that an RCT is required comparing Dynesys with fusion and conservative care. Long-term follow-up studies are required.
- One Adviser stated that the treatment effect is unproven over natural history (i.e. spine will begin to fuse with age).
- Training and facilities: one Specialist Adviser stated that personal training by a surgeon experienced in this technique is required, including cadaver training or other practical courses.

## Patient Commentators' opinions

NICE's Patient and Public Involvement Programme were unable to gather patient commentary for this procedure.

## Issues for consideration by IPAC

Future studies:

- An RCT in the US is currently recruiting patients with spinal stenosis to compare dynamic stabilisation (using Stabilimax NZ® dynamic spine stabilisation system) with fusion. The study aims to recruit 480 patients for completion by December 2010. The primary outcome measures are leg pain physical functioning, surgical revision, removal and complications. Secondary outcomes are reduction in surgical time, blood loss, length of hospital stay, quality of life and radiographic evidence of non-fusion.
- An RCT in the US is currently recruiting patients with lumbar degenerative disc disease to compare percutaneous dynamic stabilisation with fusion. The study aims to recruit 292 patients for completion by June 2010. The primary outcome measure is the Oswestry Disability Index.

# References


1. Kanayama M, Togawa D, Hashimoto T et al. (2009) Motion-preserving surgery can prevent early breakdown of adjacent segments: Comparison of posterior dynamic stabilization with spinal fusion. Journal of Spinal Disorders & Techniques 22:463–467.

2. Kim YS, Zhang HY, Moon BJ et al. (2007) Nitinol spring rod dynamic stabilization system and Nitinol memory loops in surgical treatment for lumbar disc disorders: short-term follow up. Neurosurgical Focus 22:E10.–

3. Putzier M, Schneider SV, Funk JF et al. (2005) The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone. Spine 30:E109–E114.

4. Hadlow SV, Fagan AB, Hillier TM et al. (1998) The Graf ligamentoplasty procedure. Comparison with posterolateral fusion in the management of low back pain. Spine (Phila.Pa 1976.) 23:1172–1179.

5. Kanayama M, Hashimoto T, Shigenobu K et al. (2001) Adjacent-segment morbidity after Graf ligamentoplasty compared with posterolateral lumbar fusion.[see comment]. Journal of Neurosurgery Spine 95:5–10.

6. Ozer AF, Crawford NR, Sasani M et al. (2010) Dynamic lumbar pedicle screw-rod stabilization: two-year follow-up and comparison with fusion. The open orthopaedics journal 4:137–141.

7. Cakir B, Carazzo C, Schmidt R et al. (2009) Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine. Spine 34:1287–1291.

8. Welch WC, Cheng BC, Awad TE et al. (2007) Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results. Neurosurgical Focus 22:E8.–

9. Stoll TM, Dubois G, and Schwarzenbach O. (2002) The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system. European Spine Journal 11 Suppl 2:S170–S178.

# Appendix A: Additional papers on non-rigid stabilisation techniques for the treatment of low back pain

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Saxler G, Wedemeyer C, von KM et al. (2005) [Follow-up study after dynamic and static stabilisation of the lumbar spine]. [German]. Zeitschrift fur Orthopadie und Ihre Grenzgebiete 143:92-99. | Non randomised comparative study<br><br>n= 52 (26 vs 26)<br><br>Follow-up = 79 months (mean) | No significant differences between dynamic and static stabilisation groups for oswestry disability index, low back outcome score and pain score (VAS). | Only abstract in English |
| Kaner T, Dalbayrak S, Oktenoglu T et al. (2010) Comparison of posterior dynamic and posterior rigid transpedicular stabilization with fusion to treat degenerative spondylolisthesis. Orthopedics 33: | Non randomised comparative study<br><br>n= 46 (26 vs 20)<br><br>Follow-up: 24 months | Dynamic stabilisation group: 2 complications. One screw malposition which improved following revision surgery within 1 month of the procedure. One patient had a fusion at 1 year due to continued pain.<br>Fusion group: 1 patient had adjacent segment disease requiring re-operation. | Feature article – abstract only |
| Boeree N. (2005) Dynamic stabilization of the degenerative lumbar motion segment: the Wallis system. The Spine Journal 5;4: 89S. | Case series<br><br>n= 260<br><br>Follow-up = 2 years | Mean lumbar pain score (VAS) reduced from 70.9 at baseline to 20.6 at 3 month ($p<0.01$) | Abstract only |
| Bordes-Monmeneu M, Bordes-Garcia V, Rodrigo-Baeza F et al. (2005) [System of dynamic neutralization in the lumbar spine: experience on 94 cases.]. [Spanish]. Neurocirugia (Asturias, Spain) 16:499-506. | Case series<br><br>n= 94<br><br>Follow-up = 14-24 months | Oswestry scale:<br>Preop: 56.8%<br>Follow-up: 21.4%<br>82% patients returned to work<br>Complications:<br>2 cases subcutaneous seroma and 2 late subclincal infections | Larger studies included in Table 2<br><br>Only abstract in English |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Delamarter RB, Maxwell J, Davis R et al. (2006) Nonfusion Application of the Dynesys System in the Lumbar Spine: Early Results from the IDE Multicenter Trial. The Spine Journal 6:77S- | Case series<br><br>n= 84 (Dynesys)<br><br>Follow-up: 24 months | Mean postoperative ODI at 24 months: 19.6<br><br>Intervertebral angular motion at L3-4, L4-5 and L5-SI ranged from 35% to 45% of pre-operative levels.<br><br>3 re-operations (2 fusions after expalnt for continued symptoms and 1 explant without fusion). 5% had asymptomatic radiolucency without subsequent treatment. | Larger studies included in Table 2<br><br>Abstract only |
| Plev D and Sutcliffe JC. (2005) Outcome and complications using a dynamic neutralization and stabilization pedicle screw system (DYNESYS): Is this a "soft fusion"? The Spine Journal 5:S141-S142. | Case series<br><br>n= 79 (Dynesys)<br><br>Follow-up: 12 months | ODI:<br>Pre-operative: 50.6<br>Postop: 5.7<br>Seven patients had unchanged or worse symptoms at 6 months and 4 had complaints affecting their daily living at 12 months.<br>Complications:<br>Device related: 15 cases (recurrent herniated discs, adjacent level degeneration, local muscle irritation, ossification and scoliosis).<br>Non device related: 9 cases (CSF leakage, psoas haematoma, wound haematoma and dehiscence)<br>Medical: 7 cases (infection, DVT, gastric complaints).<br>Surgical revision required: 10 patients (complete system removal in 3 patents). | Larger studies included in Table 2<br><br>Abstract only |
| Sapkas GS, Themistocleous GS, Mavrogenis AF et al. (2007) Stabilization of the lumbar spine using the dynamic neutralization system. Orthopedics 30:859-865. | Case series<br><br>n= 68<br><br>Follow-up = 36.2 months (mean) | 2 reoperations to remove implant (1 for deep infection and 1 for leg pain) and 3 patients with screw loosening. Mean Oswestry disability index improved from 55.4% at baseline to 22.9% at follow-up. | Larger studies included in Table 2 |
| Kanayama M, Hashimoto T, Shigenobu K et al. (1-3-2005) Non-fusion surgery for degenerative | Case series<br><br>n= 64 (Graf ligamentplasty) | Mean VAS (back pain):<br>Pre-operative: 71.7<br>Postoperative: 14.2<br>($p < 0.05$)<br>Mean VAS (sciatica): | Larger studies included in Table 2 |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| spondylolisthesis using artificial ligament stabilization: surgical indication and clinical results. Spine (Phila.Pa 1976.) 30:588-592. | Follow-up: 67 months (mean) | Pre-operative: 76.3<br>Postoperative: 14.5<br>($p < 0.05$)<br><br>Additional surgery for adjacent segment morbidity: 4 patients. One patient also underwent PLIF due to residual spinal instability. | |
| Hashimoto T, Oha F, Shigenobu K et al. (2001) Mid-term clinical results of Graf stabilization for lumbar degenerative pathologies. a minimum 2-year follow-up. Spine Journal: Official Journal of the North American Spine Society 1:283-289. | Case series<br><br>n= 59<br><br>Follow-up = 2 years | Mean pain score (VAS) improved from 61.7 at baseline to 18.7 at follow-up ($p<0.05$)<br>Range of motion decreased from 12° at baseline to 4.2° at follow-up ($p=0.03$)<br><br>1 case of deep wound infection | Larger studies included in Table 2<br><br>Potentially same patients as Kanayama 2001 reported in Table 2<br><br>Reported in Table 2 in original overview |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Kanayama M, Hashimoto T, Shigenobu K et al. (1997) A minimum 10-year follow-up of posterior dynamic stabilization using Graf artificial ligament. Spine 32:1992-1996. | Case series<br><br>n= 56<br><br>Follow-up = 10 years minimum | Additional surgery required in 3 patients for adjacent segmental pathologies | Larger studies included in Table 2 |
| Bothmann M, Kast E, Boldt GJ et al. (2008) Dynesys fixation for lumbar spine degeneration. Neurosurgical Review 31:189-196. | Case series<br><br>n= 54<br><br>Follow-up = 16 months (mean) | Mean back pain scores (VAS):<br>Baseline: 8.3<br>Postop: 3.4 (p<0.01)<br>Mean leg pain scores (VAS):<br>Baseline: 7.2<br>Postop: 2.9 (p<0.01)<br>1 case screw breakage at 21 months (implant removed)<br>7 cases of screw loosening (symptomatic, treated by implant removal and/or fusion) | Larger studies included in Table 2 |
| Rigby MC, Selmon GP, Foy MA et al. (2001) Graf ligament stabilisation: mid- to long-term follow-up. Eur Spine J 10:234-236. | Case series<br><br>n= 51<br><br>Follow-up = 51.7 months | Overall reoperation rate: 21% (11/51)<br>There was no significant difference in the Oswestry disability index score at baseline 46 points (range 22 to 78) and follow up 40 points (range 0 to 82)<br>41% (21/51) of patients would not chose to repeat the operation.<br><br>Operative complications:<br>Superficial wound infection: 6% (3/51)<br>Deep infection:2% (1/51)<br>Dural tear: 4% (2/51)<br>Malpositioned pedicle screw: 4% (2/51)<br><br>Post operative complications:<br>Radicular pain: 6%(3/51)<br>Failed ligament: 4% (2/51) | Larger studies included in Table 2<br><br>Reported in Table 2 in original overview |
| Grob D, Benini A, Junge A et al. (2005) Clinical experience with the Dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years. Spine 30:324-331. | Case series<br><br>n= 50<br><br>Follow-up = 2 years | 19.4% (6/31) of patients required further intervention, or were still undergoing tests in the 2-year follow-up.<br>68% of respondents indicated that they would make the same decision to undergo surgery<br>Complications: one case each of plural effusion, | Larger studies included in Table 2<br><br>Reported in Table 2 in original overview |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| | | transient mental confusion, cardiac insufficiency, and dural tear requiring suturing and sealing | |
| Grevitt MP, Gardner AD, Spilsbury J et al. (1995) The Graf stabilisation system: early results in 50 patients. Eur.Spine J 4:169-175. | Case series<br><br>n= 50 (Graf stabilisation)<br><br>Follow-up: 24 months (mean) | Oswestry disability score:<br>Pre-operative: 59%<br>Postop:31%<br><br>Clinical results:<br>Excellent/ Good: 72%<br>Fair: 10%<br>The same: 16%<br>Worse: 2%<br><br>All but 3 patients felt the surgery was worthwhile.<br><br>27 complications in 17 patients:<br>Split pedicle: 2 patients<br>Malpositioned screw: 2 patient<br>Radicular pain: 12 patients<br>Screw displacement: 1 patient<br>Screw breakage: 2 patients<br>Deep infection: 1 patient<br><br>Revision and further procedures:<br>Screw removal: 4 patients<br>Screw repositioned: 5 patients<br>Band removal: 2 patients<br>Extension of stabilisation: 2 patients<br>Anterior fusion: 4 patients | Larger studies included in Table 2 |
| Onda A, Otani K, Konno S et al. (2006) Mid-term and long-term follow-up data after placement of the Graf stabilization system for lumbar degenerative disorders. Journal of Neurosurgery Spine 5:26-32. | Case series<br><br>n= 43<br><br>Follow-up = up to 10 years | Pain scores (VAS) significantly better than preoperative scores. | Larger studies included in Table 2 |
| Choi YS. (2006) Dynamic Stabilization of Lumbar Spinal Stenosis by Use of Graf Bands: Results with Minimal 8 Years Follow-up. Journal Japanese Orthopaedic Association 8(4):S515 | Case series<br><br>n= 43<br><br>Follow-up = 8 years | 26% (18/67) segments showed change of band maintenance and 46% (31/67) segments had loss of >10% disc height at follow-up. | Larger studies included in Table 2<br><br>Abstract only |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| | | | |
| Kaner T, Sasani M, Oktenoglu T et al. (2010) Minimum two-year follow-up of cases with recurrent disc herniation treated with microdiscectomy and posterior dynamic transpedicular stabilisation. The Open Orthopaedics Journal 4:120-125. | Case series<br><br>n= 40<br><br>Follow-up: 41 months | Oswestry and VAS scores significantly improved following the joint procedure ($p < 0.01$). Complications: 1 patient with foreign body reaction which required re-operation to remove the dynamic stabilisation system. One patient had continued low back pain and sciatica. The dynamic stabilisation was removed and fusion with rigid stabilisation was performed. | Larger studies included in Table 2 |
| Acosta J, Christensen FB, Coe JD et al. (2008) Early Clinical & Radiographic Results of NFix II Posterior Dynamic Stabilization System. SAS Journal 2:69-75. | Case series<br><br>n= 40<br><br>Follow-up: 8.1 months (mean) | Mean VAS score improved from 7.6 pre-operatively to 3.3 postoperatively ($p < 0.001$). Mean ODI score improved from 47.3 to 22.8 ($p < 0.001$). 80% were severely disabled pre-operatively (ODI ≥41) which was reduced to 13% postoperatively. 53% of pre-operative segmental motion was retained at the dynamically stabilised level 6 months postoperatively. | Larger studies included in Table 2 |
| Crawford RJ, Price RI, Malone Q et al. (2009) Clinical outcomes following lumbar surgery augmented with DIAM interspinous implant. Journal of Musculoskeletal Research 12:59-69. | Case series<br><br>n= 39<br><br>Follow-up = 2 years | Clinically significant improvement in pain and function in 23.4% and 13.5% patients respectively. 28.2% (11/39) patients required further lumbar surgery. 68% (19/28) patients satisfied at follow-up. | Larger studies included in Table 2 |
| Markwalder TM and Wenger M. (2003) Dynamic stabilization of lumbar motion segments by use of Graf's ligaments: results with an average follow-up of 7.4 years in 39 highly selected, consecutive patients. Acta Neurochirurgica 145:209-214. | Case series<br><br>n= 39<br><br>Follow-up = 7.4 years | 44% (17/39) had excellent clinical evaluation after the procedure. Back pain was reported to be 'completely disappeared' in 67% (26/39) of cases 'significantly less' in 26% (10/39), 'a bit less' in 3% (3/39) | Larger studies included in Table 2<br><br>Reported in Table 2 in original overview |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| | | | |
| Floman Y, Millgram MA, Smorgick Y et al. (2007) Failure of the Wallis interspinous implant to lower the incidence of recurrent lumbar disc herniations in patients undergoing primary disc excision. J Spinal Disord.Tech. 20:337-341. | Case series<br><br>n= 37 (Wallis)<br><br>Follow-up: 16 months (mean) | ODI:<br>Pre-operative: 43<br>Postop: 12.7 ($p < 0.05$)<br><br>VAS (back pain):<br>Pre-operative: 6.6<br>Postop: 1.4 ($p < 0.05$)<br><br>VAS (leg pain):<br>Pre-operative: 8.2<br>Postop: 1.5 ($p < 0.05$)<br><br>Two out of 5 patients with relapsing leg pain had subsequent disectomy and fusion. | Larger studies included in Table 2 |
| Benezech J and Mitulescu A. (2007) Retrospective patient outcome evaluation after semi-rigid stabilization without fusion for degenerative lumbar instability. European Journal of Orthopaedic Surgery and Traumatology 17:227-234. | Case series<br><br>n= 33<br><br>Follow-up = 45 months (mean) | 76% good or excellent functional results.<br>87.5% returned to previous work<br>90% patients with preservation of both instrumented levels and adjacent ones. | Larger studies included in Table 2 |
| Lui G, Zhao J, Dezawa A. (2008) Endoscopic decompression combined with interspinous process implant fusion for lumbar spinal stenosis. Chinese Journal of Traumatology 11(6):364-367. | Case series<br><br>n= 30<br><br>Follow-up = 1 month | No difference in mean range of movement after the procedure. Back and leg pain significantly improved after the procedure ($p<0.05$) | Larger studies included in Table 2 |
| Di Silvestre M, Lolli F, Bakaloudis G et al. (15-1-2010) Dynamic stabilization for degenerative lumbar scoliosis in elderly patients. Spine 35:227-234. | Case series<br><br>n= 29<br><br>Follow-up: 54 months (mean) | ODI mean improvement: 51.7% ($p = 0.01$)<br>Roland Morris disability questionnaire mean improvement: 51.7% for leg pain ($p = 0.02$) and 57.8% for back pain ($p = 0.01$).<br>Major complications: 1 patient with a misplaced screw at L5 required revision surgery and 1 patient had junctional disc degeneration requiring revision surgery. | Larger studies included in Table 2 |
| Karadimas E, Nicol M, Siddiqui M et al. (2005) P7. Dynesys stabilization system for the treatment of patients | Case series<br><br>n= 28<br><br>Follow-up = not reported | Significant reduction in mean range of movement in lumbar spine from 37.07° at baseline to 26.37° | Larger studies included in Table 2<br><br>Abstract only |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| with discogenic low back pain. Spine Journal 5; 4:112S. | | postoperatively (p<0.005) | |
| Park H, Zhang H-Y, Cho BY et al. (2009) Change of lumbar motion after multi-level posterior dynamic stabilization with bioflex system: 1 Year follow up. Journal of Korean Neurosurgical Society 46:285-291. | Case series<br><br>n= 27<br><br>Follow-up: 1 year | VAS scores for leg and back pain decreased significantly.<br>Complications: 2 patients had screw and rod fracture, 1 patient had loosening of the cap and 2 patients had screw malpositioning and postoperative haematoma. | Larger studies included in Table 2 |
| Brechbuhler D, Markwalder TM, and Braun M. (1998) Surgical results after soft system stabilization of the lumbar spine in degenerative disc disease--long-term results. Acta Neurochir.(Wien.) 140:521-525. | Case series<br><br>n= 27 (Graf stabilisation<br><br>Follow-up: 50 months (mean) | Clinical results:<br>Excellent: 62.9%<br>Good: 11.1%<br>Satisfactory: 11.1%<br>Moderate: 7.4%<br>Poor: 7.4% | Larger studies included in Table 2 |
| Schnake KJ, Schaeren S, and Jeanneret B. (15-2-2006) Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis. Spine 31:442-449. | Case series<br><br>n= 26<br><br>Follow-up = minimum 2 years | Significant decrease in mean leg pain (p<0.01) and significant improvement in mean walking distance to more than 1000m (p<0.01)<br>17% implant failure rate (none were clinically symptomatic) | Larger studies included in Table 2 |
| Ricart O and Serwier JM. (2008) [Dynamic stabilisation and compression without fusion using Dynesys for the treatment of degenerative lumbar spondylolisthesis: a prospective series of 25 cases]. [French]. Revue de Chirurgie Orthopedique et Reparatrice de l Appareil Moteur 94:619-627. | Case series<br><br>n= 25<br><br>Follow-up = 34 months (mean) | 72 patients had very good results.<br><br>Complications:<br>Aggravation of preoperative crural paresia with complete recovery: 1 patient<br>Replacement of one neuroaggressive pedicular screw with no consequence: 1 patient | Larger studies included in Table 2<br><br>Only abstract in English |
| Beastall J, Karadimas E, Siddiqui M et al. (15-3-2007) The Dynesys lumbar spinal stabilization system: a preliminary report on positional magnetic resonance imaging findings. Spine 32:685-690. | Case series<br><br>n= 24<br><br>Follow-up = 9 months | Significant reduction in mean range of movement in lumbar spine from 13.37° at baseline to 4.08° following procedure (p=0.002) | Larger studies included in Table 2 |
| Kumar A, Beastall J, Hughes J et al. (15-12- | Case series | Significant increase in mean Woodend score | Larger studies included in Table 2 |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| 2008) Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years. Spine (Phila.Pa 1976.) 33:2909-2914. | n= 20<br><br>Follow-up = 2 years | (measurement of disc degeneration) from 1.95 before surgery to 2.52 after surgery (p<0.001) Dynesys does not stop continuing degeneration at adjacent segments. | |
| Lee S-E, Park S-B, Jahng T-A et al. (2008) Clinical experience of the dynamic stabilization system for the degenerative spine disease. Journal of Korean Neurosurgical Society 43:221-226. | Case series<br><br>n= 20<br><br>Follow-up = 27.25 months (mean) | One patient had implant removed.<br>Mean pain score (VAS) significantly decreased from 8.55 preoperatively to 2.2 postoperatively (p<0.001). No significant change in ROM. | Larger studies included in Table 2 |
| Kocak T, Cakir B, Reichel H et al. (2010) Screw loosening after posterior dynamic stabilization--review of the literature. [Review] [21 refs]. Acta Chirurgiae Orthopaedicae et Traumatologiae Cechoslovaca 77:134-139. | Case series<br><br>n= 19<br><br>Follow-up: 12 months (minimum) | Group 1: 7 patients had dynesys implanted conventionally, Group 2: 5 implanted using CT-based navigation and Group 3: 7 implanted using fluoroscopic navigation.<br>Pedicle perforation of minimum 2mm detected in 2 patients in group1, 1 patient in group 2 and 2 patients in group 3. One patient in group 1 required revision surgery due to symptomatic screw loosening. One patient in group 3 required revision surgery due to persistent pain. | Larger studies included in Table 2 |
| Kaner T, Sasani M, Oktenoglu T et al. (2009) Utilizing dynamic rods with dynamic screws in the surgical treatment of chronic instability: a prospective clinical study. Turkish Neurosurgery 19:319-326. | Case series<br><br>n= 15<br><br>Follow-up: 19 months (mean) | Significant postoperative improvements in ODI and VAS ($p < 0.05$).<br>One patient had a broken screw and required revision surgery. | Larger studies included in Table 2 |
| Sasani M, Aydin AL, Oktenoglu T et al. (2008) The Combined Use of a Posterior Dynamic Transpedicular Stabilization System and a Prosthetic Disc Nucleus Device in Treating Lumbar Degenerative Disc Disease With Disc Herniations. SAS Journal 2:130-136. | Case series<br><br>n= 13<br><br>Follow-up: 12 months | Oswestry and VAS showed significant improvement ($p < 0.05$).<br>Complications: 2 patients had the PDN device embedded in the adjacent corpus and in 1 patient the PDN device migrated to one side in the vertebral space. | Larger studies included in Table 2 |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Vaga S, Brayda-Bruno M, Perona F et al. (2009) Molecular MR imaging for the evaluation of the effect of dynamic stabilization on lumbar intervertebral discs. European Spine Journal 18: (Suppl-1):S40-S48. | Case series<br><br>n= 10<br><br>Follow-up = 6 months | Mean pain score (VAS) significantly improved from 7.6 at baseline to 3.1 following the procedure (p=0.0014). Oswestry Disability Index significantly improved from 54% at baseline to 24% after the procedure (p=0.00023). | Larger studies included in Table 2 |
| Fayyazi AH, Ordway NR, Park SA et al. (2010) Radiostereometric analysis of postoperative motion after application of dynesys dynamic posterior stabilization system for treatment of degenerative spondylolisthesis. Journal of Spinal Disorders & Techniques 23:236-241. | Case series<br><br>n= 6<br><br>Follow-up: 24 months | No significant change in degree of motion. | Larger studies included in Table 2 |

# Appendix B: Related NICE guidance for non-rigid stabilisation techniques for the treatment of low back pain

| Guidance | Recommendations |
|---|---|
| Interventional procedures | **Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedures guidance 183 (2006). [current guidance]**<br><br>**1 Guidance**<br>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.<br>1.2 Clinicians wishing to undertake non-rigid stabilisation techniques for the treatment of low back pain should take the following actions.<br>• Inform the clinical governance leads in their Trusts.<br>• 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).<br>• Audit and review clinical outcomes of all patients undergoing non-rigid stabilisation procedures for the treatment of low back pain.<br>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.<br><br>**Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedures guidance 306 (2009).**<br><br>**1 Guidance**<br>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.<br>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.<br>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 |

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| | selection and the need for further surgery.<br><br>**Percutaneous intradiscal electrothermal therapy for lower back pain. NICE interventional procedures guidance 319 (2009).**<br><br>**1 Guidance**<br>1.1 Current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.<br>1.2 Clinicians wishing to undertake percutaneous intradiscal electrothermal therapy for low back pain should take the following actions.<br>• Inform the clinical governance leads in their Trusts.<br>• 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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG319publicinfo).<br>• Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for low back pain (see section 3.1).<br>1.3 NICE encourages further research into percutaneous intradiscal electrothermal therapy for low back pain. Research should describe patient selection, use validated measures of long-term pain relief and quality of life, address the role of the procedure in avoiding major surgery, and measure long-term safety outcomes.<br><br>**Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedures guidance 321 (2009).**<br><br>**1 Guidance**<br>1.1 Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.<br>1.2 Clinicians wishing to undertake lateral interbody fusion in the lumbar spine should take the following actions.<br>• Inform the clinical governance leads in their Trusts.<br>• 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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG321publicinfo).<br>• Audit and review clinical outcomes of all patients having lateral interbody fusion in the lumbar spine (see section 3.1).<br>1.3 This procedure should only be carried out by surgeons with specific training in the technique, who should perform their initial procedures with an experienced mentor.<br>1.4 NICE encourages further research into lateral interbody fusion in the lumbar spine. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and |

late complications. NICE may review the procedure on publication of further evidence.

**Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedures guidance 300 (2009).**

**1 Guidance**

1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate 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 percutaneous endoscopic laser lumbar discectomy should take the following actions.

- Inform the clinical governance leads in their 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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG300publicinfo).
- Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy (see section 3.1).

1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal.

1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data.

**Percutaneous disc decompression using coblation for lower back pain. NICE interventional procedures guidance 173 (2006).**

**1 Guidance**

1.1 Current evidence suggests that there are no major safety concerns associated with the use of percutaneous disc decompression using coblation for lower back pain. There is some evidence of short-term efficacy; however, this is not sufficient to support the use of this procedure without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake percutaneous disc decompression using coblation for lower back pain should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended (available from www.nice.org.uk/IPG173publicinfo).
- Audit and review clinical outcomes of all patients having percutaneous disc decompression using coblation for lower back pain.

1.3 Further research will be useful in reducing the current uncertainty, and clinicians are encouraged to collect long-term follow-up data. The Institute may review the procedure upon publication of further evidence.

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| | **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedures guidance 141 (2005).**<br><br>**1 Guidance**<br>1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research.<br>1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions.<br>• Inform the clinical governance leads in their Trusts.<br>• Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's *Information for the public* is recommended.<br>• Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence.<br><br>**Percutaneous intradiscal radio frequency thermo coagulation for lower back pain. NICE interventional procedures guidance 83 (2004).**<br><br>**1 Guidance**<br>1.1 Current evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.<br>1.2 Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation for lower back pain should take the following actions.<br>• Inform the clinical governance leads in their Trusts.<br>• Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.<br>• Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency thermocoagulation for lower back pain.<br>1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.<br><br>**Percutaneous endoscopic laser thoracic discectomy. NICE interventional procedures guidance 61 (2004).**<br><br>**1 Guidance**<br>1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser thoracic discectomy does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.<br>1.2 Clinicians wishing to undertake percutaneous endoscopic laser thoracic discectomy should take the following action. |

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| | • Inform the clinical governance leads in their Trusts.<br>• 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.<br>• Audit and review clinical outcomes of all patients having percutaneous endoscopic laser thoracic discectomy.<br>1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.<br><br>**Laser lumbar discectomy. NICE interventional procedures guidance 27 (2003). (currently under review)**<br><br>**1 Guidance**<br>1.1 Current evidence on the safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laser lumbar discectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.<br><br>**Endoscopic laser foraminoplasty. NICE interventional procedures guidance 31 (2003).**<br><br>**1 Guidance**<br>1.1 Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present. |

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| Clinical guidelines | **Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009).**<br><br>**1 Guidance**<br>***1.1 Assessment and imaging***<br>1.1.1 Keep diagnosis under review.<br>1.1.2 Do not offer X-ray of the lumbar spine for the management of non-specific low back pain.<br>1.1.3 Consider MRI (magnetic resonance imaging) when a diagnosis of spinal malignancy, infection, fracture, cauda equina syndrome or ankylosing spondylitis or another inflammatory disorder is suspected.<br>1.1.4 Only offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion (see section 1.9).<br>***1.2 Information, education and patient preferences***<br>1.2.1 Provide people with advice and information to promote self-management of their low back pain.<br>1.2.2 Offer educational advice that:<br>• includes information on the nature of non-specific low back pain<br>• encourages the person to be physically active and continue with normal activities as far as possible.<br>1.2.3 Include an educational component consistent with this guideline as part of other interventions, but do not offer stand-alone formal education programmes.<br>1.2.4 Take into account the person's expectations and preferences when considering recommended treatments, but do not use their expectations and preferences to predict their response to treatments.<br>1.2.5 Offer one of the following treatment options, taking into account patient preference: an exercise programme (see section 1.3.3), a course of manual therapy (see section 1.4.1) or a course of acupuncture (see section 1.6.1). Consider offering another of these options if the chosen treatment does not result in satisfactory improvement.<br>***1.3 Physical activity and exercise***<br>1.3.1 Advise people with low back pain that staying physically active is likely to be beneficial.<br>1.3.2 Advise people with low back pain to exercise.<br>1.3.3 Consider offering a structured exercise programme tailored to the person:<br>• This should comprise up to a maximum of eight sessions over a period of up to 12 weeks.<br>• Offer a group supervised exercise programme, in a group of up to 10 people.<br>• A one-to-one supervised exercise programme may be offered if a group programme is not suitable for a particular person.<br>1.3.4 Exercise programmes may include the following elements:<br>• aerobic activity<br>• movement instruction<br>• muscle strengthening<br>• postural control<br>• stretching.<br>***1.4 Manual therapy*** |

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| | The manual therapies reviewed were spinal manipulation (a low-amplitude, high-velocity movement at the limit of joint range that takes the joint beyond the passive range of movement), spinal mobilisation (joint movement within the normal range of motion) and massage (manual manipulation or mobilisation of soft tissues). Collectively these are all manual therapy. Mobilisation and massage are performed by a wide variety of practitioners. Manipulation can be performed by chiropractors and osteopaths, as well as by doctors and physiotherapists who have undergone specialist postgraduate training in manipulation.<br>1.4.1 Consider offering a course of manual therapy, including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks.<br>***1.5 Other non-pharmacological therapies***<br>**Electrotherapy modalities**<br>1.5.1 Do not offer laser therapy.<br>1.5.2 Do not offer interferential therapy.<br>1.5.3 Do not offer therapeutic ultrasound.<br>**Transcutaneous nerve stimulation**<br>1.5.4 Do not offer transcutaneous electrical nerve simulation (TENS).<br>**Lumbar supports**<br>1.5.5 Do not offer lumbar supports.<br>**Traction**<br>1.5.6 Do not offer traction.<br>***1.6 Invasive procedures***<br>1.6.1 Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks.<br>1.6.2 Do not offer injections of therapeutic substances into the back for non-specific low back pain.<br>***1.7 Combined physical and psychological treatment programme***<br>1.7.1 Consider referral for a combined physical and psychological treatment programme, comprising around 100 hours over a maximum of 8 weeks, for people who:<br>• have received at least one less intensive treatment (see section 1.2.5) **and**<br>• have high disability and/or significant psychological distress.<br>1.7.2 Combined physical and psychological treatment programmes should include a cognitive behavioural approach and exercise.<br>***1.8 Pharmacological therapies***<br>Both weak opioids and strong opioids are discussed in the recommendations in this section. Examples of weak opioids are codeine and dihydrocodeine (these are sometimes combined with paracetamol as co-codamol or co-dydramol, respectively). Examples of strong opioids are buprenorphine, diamorphine, fentanyl and oxycodone. Some opioids, such as tramadol, are difficult to classify because they can act like a weak or strong opioid depending on the dose used and the circumstances.<br>No opioids, cyclooxygenase 2 (COX-2) inhibitors or tricyclic antidepressants and only some non-steroidal anti-inflammatory drugs (NSAIDs) have a UK marketing authorisation for treating low back pain. If a drug without a marketing authorisation for this indication is prescribed, informed consent should be obtained and documented. |

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| | 1.8.1 Advise the person to take regular paracetamol as the first medication option.<br>1.8.2 When paracetamol alone provides insufficient pain relief, offer:<br>• non-steroidal anti-inflammatory drugs (NSAIDs) **and/or**<br>• weak opioids<br>Take into account the individual risk of side effects and patient preference.<br>1.8.3 Give due consideration to the risk of side effects from NSAIDs, especially in:<br>• older people<br>• other people at increased risk of experiencing side effects.<br>1.8.4 When offering treatment with an oral NSAID/COX-2 (cyclooxygenase 2) inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor. In either case, for people over 45 these should be co-prescribed with a PPI (proton pump inhibitor), choosing the one with the lowest acquisition cost. [This recommendation is adapted from 'Osteoarthritis: the care and management of osteoarthritis in adults' (NICE clinical guideline 59).]<br>1.8.5 Consider offering tricyclic antidepressants if other medications provide insufficient pain relief. Start at a low dosage and increase up to the maximum antidepressant dosage until therapeutic effect is achieved or unacceptable side effects prevent further increase.<br>1.8.6 Consider offering strong opioids for short-term use to people in severe pain.<br>1.8.7 Consider referral for specialist assessment for people who may require prolonged use of strong opioids.<br>1.8.8 Give due consideration to the risk of opioid dependence and side effects for both strong and weak opioids.<br>1.8.9 Base decisions on continuation of medications on individual response.<br>1.8.10 Do not offer selective serotonin reuptake inhibitors (SSRIs) for treating pain.<br>***1.9 Referral for surgery***<br>1.9.1 Consider referral for an opinion on spinal fusion for people who:<br>• have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) **and**<br>• still have severe non-specific low back pain for which they would consider surgery.<br>1.9.2 Offer anyone with psychological distress appropriate treatment for this before referral for an opinion on spinal fusion.<br>1.9.3 Refer the patient to a specialist spinal surgical service if spinal fusion is being considered. Give due consideration to the possible risks for that patient.<br>1.9.4 Do not refer people for any of the following procedures:<br>• intradiscal electrothermal therapy (IDET)<br>• percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)<br>• radiofrequency facet joint denervation. |

# Appendix C: Literature search for non-rigid stabilisation techniques for the treatment of low back pain

| Databases | Date searched | Version/files |
|---|---|---|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library) | 27/07/2010 | July 2010 |
| Database of Abstracts of Reviews of Effects – DARE (CRD website) | 27/07/2010 | N/A |
| HTA database (CRD website) | 27/07/2010 | N/A |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 27/07/2010 | July 2010 |
| MEDLINE (Ovid) | 27/07/2010 | 1950 to July Week 2 2010 |
| MEDLINE In-Process (Ovid) | 27/07/2010 | July 26, 2010 |
| EMBASE (Ovid) | 27/07/2010 | 1980 to 2010 Week 29 |
| CINAHL (NLH Search 2.0 or EBSCOhost) | 27/07/2010 | N/A |
| BLIC (Dialog DataStar) | 27/07/2010 | N/A |
| Zetoc | 27/07/2010 | N/A |

| **Websites** | **Date searched** | **Title, year and link** |
|---|---|---|
| NICE ('published' and 'in development' guidance) | 13/10/2009 | Prosthetic intervertebral disc replacement in the lumbar spine (IPG306), 2009<br><br>Interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine (IPG165), 2006<br><br>Non-rigid stabilisation techniques for the treatment of low back pain (IPG183), 2006 |
| FDA (MAUDE database) | 13/10/2009 | None found |
| ASERNIP | 13/10/2009 | Horizon scanning technology prioritising summary, 2006 |
| ANZHSN | 13/10/2009 | None found |
| National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database | 13/10/2009 | None found |
| Current Controlled Trials *meta*Register of Controlled Trials - *m*RCT | 13/10/2009 | Flexible or solid stabilisation for lumbar spondylosis?<br>A randomised controlled trial - Stage 1 - Feasibility Study |

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| | | 2004 |
| Clinicaltrials.gov | 13/10/2009 | Effects of X-STOP® Versus Laminectomy Study<br><br>Dynamic Stabilization for Lumbar Spinal Stenosis With Stabilimax NZ® Dynamic Spine Stabilization System<br><br>Wallis Stabilization System for Low Back Pain<br><br>Wallis Mechanical Normalization System for Low Back Pain<br><br>IDE Clinical Trial Comparing Coflex vs. Fusion to Treat Lumbar Spinal Stenosis<br><br>A Clinical Study of the GO-LIF™ Approach for Lumbar Spinal Fixation<br><br>Posterior Lateral Fusion (PLF) With Dynesys<br><br>Percutaneous Dynamic Stabilization (PDS) System Versus Fusion for Treating Degenerative Disc Disease<br><br>Treatment of Lumbar Spinal Stenosis; Comparison of Two Different Surgical Methods; Mini-invasive Decompression to X-stop<br><br>Long-Term Outcomes for Lumbar Spinal Stenosis Patients Treated With X STOP®<br><br>Study of the Safety and Effectiveness of DIAM™ Spinal Stabilization System vs. Decompression<br><br>A Clinical Study of the Dynesys(R) Spinal System<br><br>Greenwich Lumbar Stenosis SLIP Study<br><br>Condition of Approval Study |

Websites searched on 14 10 2009

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database

- Australian Safety and Efficacy Register of New Interventional Procedures – surgical (ASERNIP-S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites
- General internet search

**MEDLINE search strategy**

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

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| 1 | (flexi* adj3 (screw* or implant* or device* or instrument*)).tw. |
| 2 | (rotat* adj3 (screw* or implant* or device* or instrument*)).tw. |
| 3 | (dynesis or dynesys).tw. |
| 4 | dynamic neutrali?ation system*.tw. |
| 5 | (dynamic adj2 (fus* or stabili*)).tw. |
| 6 | or/1-5 |
| 7 | (interspin* adj3 implant*).tw. |
| 8 | (graf* adj3 soft* adj3 stabili* adj3 system*).tw. |
| 9 | orthopedic fixation devices/ or bone nails/ or bone plates/ or bone screws/ or bone wires/ or internal fixators/ or splints/ or suture anchors/ |
| 10 | (orthoped* adj3 fix* adj3 device*).tw. |
| 11 | (bone* adj3 (Nail* or Plate* or Screw* or Wire*)).tw. |
| 12 | (internal adj3 fix*).tw. |
| 13 | splint*.tw. |
| 14 | (suture* adj3 anchor*).tw. |
| 15 | exp ARTHRODESIS/ |
| 16 | arthrodesis*.tw. |
| 17 | (Spin* adj3 Fus*).tw. |
| 18 | exp LAMINECTOMY/ |
| 19 | laminectom*.tw. |
| 20 | exp Lumbar Vertebrae/su [Surgery] |

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| 21 | (Lumbar* adj3 Vertebr*).tw. |
| 22 | ((lumbar or pedicle) adj3 fus*).tw. |
| 23 | ((ligament* or fusion*) adj3 (bone graft or pedical screw) adj3 lumbar).tw. |
| 24 | Intervertebral Disk/ |
| 25 | "Prostheses and Implants"/ |
| 26 | 24 and 25 |
| 27 | (prosthet* adj3 (Interverteb* adj3 (Disc or disk))).tw. |
| 28 | or/7-23 |
| 29 | 28 or 26 or 27 |
| 30 | (flexib* or dynamic or non-rigid or non rigid).tw. |
| 31 | 29 and 30 |
| 32 | 6 or 31 |
| 33 | exp Spinal Stenosis/ |
| 34 | (spin* adj3 stenos*).tw. |
| 35 | (low* adj3 back* adj3 pain*).tw. |
| 36 | Low Back Pain/ or failed back surgery syndrome/ |
| 37 | exp spondylolysis/ or spondylolisthesis/ |
| 38 | spondylolisthesis.tw. |
| 39 | spondylolysis.tw. |
| 40 | (lumbar* adj3 decompress*).tw. |
| 41 | (lumbar adj3 dis* adj3 disease*).tw. |
| 42 | degenerative dis* disease*.tw. |
| 43 | ((Disc or disk) adj3 herniat*).tw. |
| 44 | listhesis*.tw. |
| 45 | (flexion* adj3 instab*).tw. |
| 46 | or/33-45 |
| 47 | 32 and 46 |

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| 48 | FASS.tw. |
| 49 | diam implant*.tw. |
| 50 | interspinous U.tw. |
| 51 | x-stop.tw. |
| 52 | mims.tw. |
| 53 | (wallis adj5 stabili*).tw. |
| 54 | or/48-53 |
| 55 | 47 or 54 |
| 56 | limit 55 to ed=20050401-20091001 |
| 57 | animals/ not humans/ |
| 58 | 56 not 57 |