NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

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

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 July 2005.

Procedure names

- Flexible stabilisation implants.
- Dynamic stabilisation.
- Soft stabilisation.

Specialty societies

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

Description

Indications

Chronic low back pain is most often the result of normal wear and tear (degenerative change) which affects everyone to some extent during their middle years causing dehydration of the intervertebral discs, reduction of spinal disc height and spinal facet joint arthrosis. The back pain is thought to arise from minor abnormal movements in disturbed joints, and may be aggravated by normal activities..

Current treatment and alternatives

Acute lower back pain can be treated by muscle relaxants, or analgesic therapy. Chiropractic intervention and posture training can limit episode of acute pain. Education, lifestyle change, weight loss, general fitness and specific low-back training may be required. Injection therapy including epidural and facet joint steroid injections may be used.

For cases of severe life-limiting chronic low back pain refractory to conservative interventions, surgery may be appropriate and includes a variety of operations designed to immobilise painful segments by bony fusion.Solid spinal fusion cannot be reversed and abnormal load patterns may cause later problems in adjacent sections. Insertion of a prosthetic intervertebral disc is one alternative in an attempt to create comfort whist preserving lumbar mobility, and hopefully reducing long term adjacent degenerative change.

What the procedure involves

Non rigid (otherwise known as flexible or dynamic) stabilisation of the lumbar spine is an alternative whereby movement and load bearing of a spinal motion segment is supported without fusing the segment in question. The systems intend to restrict motions in the direction that produces pain but allow for a full range of motion in other directions[1].

A number of devices are being investigated which depend on different biomechanical principles. Examples of these are the Bronsard and Graf ligaments which rely on synthetic cords that loop around the spinal processes. Other dynamic stabilisation devices such as the FASS and Dynesys systems are rooted by pedicle screws. Interspinous implants include the Diam, the Mims device eth interspinous ‘U’, the Wallis and the X-stop[1].

The insertion of the Dynesis system involves surgery with a pedicle screw positioned at the conventional site, and decompression, removing a portion of bone over the nerve root is performed where indicated. The system consists of titanium alloy screws, polyester cords, and spacers between screw heads. The stabilising cord connects the pedicle screw heads through a hollow core in the spacers and holds these in place. System pre-load provides a uniform rigidity, and the stabilizing cord caries tensile forces otherwise carried by the spine. The inherent stability of the whole construct also resists bending and shear forces. The most frequently operated segment is at L4/L5. Postoperative bracing is applied only in exceptional circumstances.

The Diam implant conforms to the interspinous anatomy and allows placement with minimal disturbance to the segmental muscles. Two independent laces fasten the device to the adjacent vertebrae to stabilize them in order to optimize banding strength in flexion. The patient is positioned prone on the operating table. After identification of the interspinous space, resection of the remnants of the interspinous ligament is carried out down to the ligamentum flavum. A distractor is used to spread the overlapping laminae. The implant is inserted and driven to the opposite side with a specific inserter. The most frequently involved level is L4-L5.

Efficacy

In a case series of 83 patients (the majority with spinal stenosis) receiving an implant 48% (35/73) were totally incapacitated at baseline but only 3% (2/73) remained so at

a mean follow up of 38 months. Disability scores fell from an initial 55% to 23% at the same follow up time[2]. In a smaller series of 31 cases followed up to 2 years, 67% of patients reported that back symptoms had resolved or improved and 3% reported these getting worse[3].

In a comparative study comparing a soft stabilisation system with fusion, patients treated with a ligament system demonstrated a greater range of movement at the L4-5 level (4.3° change from baseline) compared to patients treated with fusion (0.4°) ($p<0.05$). X-ray evaluation found significantly less disc deterioration at the L2-3 level with dynamic stabilisation than with fusion, however the difference at other levels was not significant[4]. In a case series of 59 patients having the same device implanted low back pain was reduced was reduced from 61.7 points at baseline to 18.7 points at 41 months follow up using a visual analogue scale[5].

Safety

Device durability outcomes following the implant of a dynamic stabilisation system showed screw loosening in 4% (7/280) of screws during 38 months of follow up, 13% (11/83) of patients required further surgery, of which 8 patients had the implant removed[2]. In another series, 10% (3/31) of cases had malpositioned screws and 3% (1/31) showed screw loosening. In the same study there was one case each of plural effusion, transient confusion, cardiac insufficiency, and dural tear[3].

At over 5 years follow up in a retrospective case series dural tears occurred in 4% (2/51) of patients and the reoperation rate was 21% (11/51)[6].

In a compariative study of patients undergoing ligament implant or fusion, additional surgery for adjacent level degeneration or spinal stenosis was required in 6% (1/18) and 19% (5/27) of cases respectively[4].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to non-rigid stabilisation. Searches were conducted via the following databases, covering the period from their commencement to 1 April 2005: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these 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 included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with low back pain.
Intervention/test	Non-rigid stabilisation devices.
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 one historically controlled trial[4], and five case series[2;3;5-7].

Existing reviews on this procedure

No systematic reviews of evidence-based guidelines on non-rigid stabilisation techniques for the treatment of low back pain were located during literature searching.

Table 1 Summary of key efficacy and safety findings on non-rigid stabilisation techniques for the treatment of low back pain

Abbreviations used: JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; SD, standard deviation; SF-36, medical outcomes short form-36; MRI, magnetic resonance imaging.

Study details	Key efficacy findings	Key safety findings	Comments
Stoll TM (2002) [2] Case series Switzerland 83 patients (n = 50) with spinal stenosis. Consecutive sample Dynesys implant. A pedicle screw system for mobile stabilisation, consisting of titanium alloy screws connected by an elastic synthetic compound Inclusion criteria: neurogenic, radicular pain or chronic lower back pain resistant to conservative treatment, presenting with some form of instability Mean age at operation 58.2 years (range 26.8–85.3 years). Male = 41%. Previous lumbar surgery had been carried out in 36% (30/83) of patients Surgery performed using a mid-line approach with the pedicle screw positioned at the Magerl site. Decompression was performed where indicated. Postoperative bracing applied only in exceptional cases Follow-up: mean 38.1 months (range 11.2–79.1 months). Assessment at follow-up performed by independent examiners, 73 patients available for follow-up, 2 patients died, and 8 patients had implant removed	**Prolo score, an index of functional and economic status** 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 There were no patients in the highest category 'all previous sports and social activities' at baseline, there were 13.7% (10/73) after the implant 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 **Pain, measured on a visual analogue scale (1–10)** At baseline the mean score for lower back pain was 7.4 (± 2.6) and after the insertion of the implant this was 3.1 (± 2.3) ($p < 0.01$) For leg pain there was an improvement from 6.9 (± 3.0) to 2.4 (± 2.1) ($p < 0.01$) **Oswestry Disability Index (0–100% scale), low scores indicate less disability** Pre-operative mean score was 55.4% (± 19.5%). At follow-up this had improved to 22.9% (± 19.3%) ($p < 0.01$)	**Device durability** Of the 83 operations undertaken, 2 had screw misplacement; 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 **Complications of surgery** Complications not relating to the implant included two cases of dural lesion (of which one was re-operated). Other complications included one case each of infection, paresis, hypesthesia, seroma, scar neuroma, cardiovascular complication and thromboembolism Only one case of infection was reported and this was superficial **Later additional surgery** During the follow-up period 13% (11/83) of patients required further surgery. Eight had a complete implant removal; three of these had unresolved persistent pain. Two patients required extension of the Dynesys implant to adjacent sections for additional stenosis. Two adjacent section decompressions were undertaken with one patient later fused. A laminectomy of the index segment was undertaken in one patient	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. Not stated that any efficacy symptom assessments have been validated for this condition. This was the first series of patients and a learning curve in operative technique can be expected. Comparison of evidence of overload sequelae from fusion studies is not possible due to differing study parameters.

Abbreviations used: JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; SD, standard deviation; SF-36, medical outcomes short form-36; MRI, magnetic resonance imaging.

Study details	Key efficacy findings	Key safety findings	Comments
Hashimoto T (2001) [5] Case series – retrospective Japan n = 59 Patients treated with Graf ligament. Single level stabilisation = 46, two level stabilisation = 13 Consecutive patients with persistent functional incapacity and neurological deficits after 3 months of conservative treatment Degenerative spondylolisthesis = 29, spinal stenosis with sagittal flexion instability = 18, disc herniations with sagittal flexion instability = 12 Age =61 years, male = 51% Follow-up = 3 years 5 months	**Clinical results** Evaluated using the JOA score (based on subjective symptoms, clinical signs and activities of daily living) and by a VAS on a 1–100 scale JOA: Baseline 12.2 (± 3.9); Discharge 23.5 (± 3.7); Final follow-up 24.2 (± 3.7); p 0.03 VAS: Baseline 61.7; Discharge Not reported; Final follow-up 18.7; p < 0.05 **Radiological evaluation** Sagittal alignment: Baseline 10.5 (± 6.1°); Discharge 14.9 (± 5.8°); Final follow-up 13.3 (± 6.0°); p <0.05 Range of movement: Baseline 12.0 (± 6.2°); Discharge Not reported; Final follow-up 4.2 (± 4.0°); p 0.03 **Operative parameters** The mean operation time was 87.3 minutes (± 37 minutes)	**Complications** Deep wound infection occurred in 2%(1/59) of the cases and required continuous irrigation No cases of device failure or neurological deterioration were reported	The surgery was performed by one of two surgeons. No cases lost to follow-up. JOA score for clinical assessment may not have been validated. All clinical outcomes rely on subjective self assessment. Not stated what degree of external support was provided postoperatively. A highly selected patient cohort. No long-term follow-up to demonstrate a benefit of low adjacent segment morbidity.

Abbreviations used: JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; SD, standard deviation; SF-36, medical outcomes short form-36; MRI, magnetic resonance imaging.

Study details	Key efficacy findings	Key safety findings	Comments
Markwalder T M (2003)[7] Case series – retrospective Switzerland n = 39 Treatment with the Graf soft stabilisation system, with a probatory jacket worn for 2 or 3 weeks following surgery and a rehabilitation programme for training lower back muscles Younger patients with a mechanical disorder of one or more lumbar segments, refractory to 6 months of conservative treatment. Symptoms of irritation of the facet joints with or without pseudo-radicular pain the in lower limbs Age = 34 years, male = 33% Follow–up: 7.4 years	**Clinical outcomes** Patients completed a questionnaire consisting of the Oswestry Disability Questionnaire (ODQ), the SF-36, the Modified Somatic Perception Questionnaire (MSPQ), the Zung Depression scale, and VAS Results were classified into excellent, good, fair, unchanged, and worse categories based on clinical evaluation and questionnaire results Excellent 44% (17/39) Good 21% (8/39) Fair 10% (4/39) Unchanged 23% (9/39) Worse 2% (1/39) Of the nine patients with unchanged score, seven underwent fusion and two had the implant removed. The one patient who had a worse score at final follow-up had been rated as ‘excellent’ at 2 years, and refused further interventions Back bain 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) Analgesics were not being used in 71.8% of patients, used occasionally in 32.1% and used daily in 5.1% The VAS for back pain was 0 in 69.2% of cases, 2.5 in 15.4% and 5 in 15.4% (length of scale not stated)	**Complications** There were no intraoperative or postoperative complications reported	5% (2/41) of patients lost to follow-up, no reasons stated. All interventions undertaken by the same surgeon. Arbitrary grouping of clinical outcomes for analysis. No outcome assessment was made by an independent clinician. No analysis of change from baseline scores. The Graf system was chosen as the intervention of choice in only 41 of 1000 cases of operations on the lumbar spine, making this a highly selected cohort.

Abbreviations used: JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; SD, standard deviation; SF-36, medical outcomes short form-36; MRI, magnetic resonance imaging.

Study details	Key efficacy findings	Key safety findings	Comments
Kanayama M (2001) [4] Comparative study – retrospective Japan n = 45 (18 Graf implants) Graft ligament, or fusion using a bone graft and pedicle screw instrumentation Patients with spondylolisthesis or flexion instability requiring stabilisation Degenerative spondylolisthesis = 29, spinal stenosis = 6, disc herniations = 10, isthmic olisthesis = 4, recurrent disc herniation = 4 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 Age =57 years, male = 49%. Follow up = 71 months	**Radiographic evaluation** 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 **Graf** / **Fusion** / **p** Global lumbar lordosis: 36.1 (± 16.0 °) / 40.6 (± 15 °) / NS Level 4–5 Range of movement: 4.3 (± 3.3°) / 0.4 (± 1.4°) / < 0.05 The rate of adjacent disc deterioration by X-ray assessment was statistically higher with fusion (~36%) than with the Graf ligament (~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 MRI evaluation of adjacent discs found no significant difference between the groups in the incidence of deterioration from baseline **Clinical evaluation** Additional surgery was required for adjacent level disc lesion, disc herniation or spinal stenosis in 6% (1/18) of cases in the Graf group and 19% (5/27) of the fusion group, to 5 years follow-up	Not reported	Follow-up rate of patients available for analysis was 64%. Not stated how others lost to follow-up. Radiological evaluation undertaken by an independent assessor. Not a randomised or sequential allocation to treatment group. Patients treated on basis of clinical presentation, and therefore were not comparable at baseline. Only patients with mild degenerative spondylolisthesis were included in the Graf group in the study. Potentially the same cases as some included in Hashimoto (2001)

Abbreviations used: JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; SD, standard deviation; SF-36, medical outcomes short form-36; MRI, magnetic resonance imaging.

Study details	Key efficacy findings	Key safety findings	Comments
Grob D (2005) [3] Case series – retrospective Switzerland n = 31 (50 including cases with less than 2 years of follow-up) Dynesys system implanted to restabilise segments, keeping them mobile within a controlled range. 33% had one level instrumented, 52% 2 levels, 13% 3 levels, 3% four levels Soft brace employed after surgery until wound healing occurred Patients with degenerative disease resulting in instability associated with neurogenic or radicular pain and or chronic back pain Spondylolisthesis = 11, spinal stenosis = 7, disc degeneration = 7, failed back surgery = 4, listhesis = 1, extradural tumour = 1 Age = 50 years, male = 35%, mean back pain 7.0 on VAS (0–10 scale) Follow up: 2 years or more	**Patient reported outcomes** All outcomes were evaluated by a patient completed questionnaire At 2 years follow-up the mean back pain intensity was 4.7 (SD 3.20) for back pain and 3.8 (SD 3.6) for leg pain. Comparisons not made with baseline scores as these were generated during consultation with a physician rather than independently **Resolved / Improved / Unchanged / Worse** back symptoms: 20% / 47% / 30% / 3% leg symptoms: 32% / 32% / 21% / 14% Quality of life: N/A / 50% / 37% / 13% (absolute figured not reported) Patient overall self-rating of global outcome following implant was 'helped a lot' 29%, 'helped' 23%, 'only helped a little' 10%, 'didn't help' 35%, 'made things worse' 3% 68% of respondents indicated that they would make the same decision to undergo surgery, and 32% would not	**Complications** There were four operative complications, and one case each of plural effusion, transient mental confusion, cardiac insufficiency, and dural tear requiring suturing and sealing 195 (6/31) of patients required further intervention, or were still undergoing tests in the 2-year follow-up. Three of these required device explant, of which two underwent rigid fusion. One patient required a morphine pump at 12 months **Technical failure** In three cases, screws were malpositioned, and in one case there was evidence of screw loosening	Three different surgeons carried out the procedures. 35% (11/31) of cases had had prior decompression and/or fusion. 42% had decompression in addition to Dynesys implant. Results presented on intention to treat basis. No quantitative comparison of changes in outcome from baseline values. No efficacy findings were significantly different if the whole group (n = 50) was analysed with a mean follow-up of 25 months. Authors state that mechanism of action is still unclear Sample size too small to undertake multivariate analysis of factors that may predict a successful outcome. No data to confirm benefit in terms of sparing adjacent level deterioration.

Abbreviations used: JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; SD, standard deviation; SF-36, medical outcomes short form-36; MRI, magnetic resonance imaging.

Study details	Key efficacy findings	Key safety findings	Comments
Rigby M C (2001) [6] Case series - retrospective UK n=51 Cases treated 1993 to 1997 Patients with low back pain, refractory to conservative management. 8 patients had previously had discectomy Stabilisation by Graf ligament. n=31 had one level stabilisation, n=17 2 levels, n=3 had 3 levels Age =41 years, Male =55% Outcomes assessed by postal questionnaire to establish Oswestry disability index, and grade success on a visual analogue scale (0 to 10 (best)) Follow up = 51.7 months	**Functional capacity** 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) **Patient satisfaction with outcome** The mean patient rating of outcome was 5 points (range 0 to 10) on a visual analogue score. 41% (21/51) of patients would not chose to repeat the operation. **Operative Characteristics** The mean length of hospital stay was 9 days (range 4 to 19 days) The overall reoperation rate was 21% (11/51)	**Complications** Complication — Rate **Operative** Superficial wound infection — 6% (3/51) Deep infection (requiring explanation) — 2% (1/51) Dural tear — 4% (2/51) Malpositioned pedicle screw — 4% (2/51) **Post operative** Radicular pain — 6%(3/51) Failed ligament — 4% (2/51)	Two surgeons carried out all the procedures. No details of initial case selection criteria 74% (51/69) response rate from initial cohort No objective measures of clinical outcomes are reported

Validity and generalisability of the studies

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr Douglas Wardlow, Mr Sindney Marks, Mr James Wilson McDonald, Mr Jeremy Fairbank, Mr John Fowler, Mr Jonathan Johnson, Mr Phillip Sell, Mr Jake Timothy. Mr Gordon Findlay

- Four advisors considered this procedure to be a minor variation on an established procedure, three suggested that it is established and two defined it as a novel procedure of uncertain safety and efficacy.

- The potential benefits of the procedure are to deliver a reduction in back pain, reduce functional disability and enable return to work, while reducing the likelihood of adjacent segment failure that may result from alternative procedures.

- Malpositioned or broken screws leading to nerve root damage, infection, cerebral-spinal fluid leak, failure of the bone/implant interface and failure to control pain have all been reported events.

- Additional theoretical events identified by advisors include device failure (particularly long term), increased lordosis, and dural root damage due to loose or misaligned screws.

- Patient selection may be vital for successful outcome, and indications for this procedure are currently poorly defined.

- Ongoing studies include the MRC spine stabilisation trial including Graf ligament cases, the FLESS trial comparing Dynesys with fusion, FDA review multicentre trial, and a manufacturer-sponsored trial of Dynesys compared with discectomy alone, fusion, or rehabilitation.

- This procedure may be undertaken concurrently with disc decompression or discectomy. It is therefore difficult to determine what clinical benefit is derived from the implant itself.

- There is little data available on long-term efficacy.

- The majority of advisors commented that implantation is relatively straightforward for surgeons experienced in pedicle screw insertion, however clinicians need to be aware of the indications for which this procedure is appropriate.

- If the procedure fails to provide clinical benefit there is likely to be no advantage from repeating the same procedure.

Issues for consideration by IPAC

The NICE Interventional Procedures programme has produced guidance on prosthetic intervertebral disc replacement http://www.nice.org.uk/ipcat.aspx?c=56892

Dynesys has FDA Class III (pre-market approval) for use to provide immobilisation and stabilisation of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurological impairment. It is not specifically indicated for lumbar stenosis.

On 31 August 2004, the Orthopaedic and Rehabilitation Devices Panel recommended to the FDA that the pre-market approval be found 'not approvable'. The panel cited concern about the need to identify the patient population that is most likely to benefit from the device, noting that overall effectiveness was not demonstrated in a majority of the clinical study population. The panel also cited concerns with the longer-term effectiveness of the device (longer than 2 years).

Limitation of further progress of spinal deformity, which is commonly associated with degenerative disease, by interspinal implant cannot be adequately assessed without longer-term follow-up

Additional data is available regarding the use of Dynesys following routine discectomy, although there may be a significantly different safety profile for the use of this procedure in such cases.

References

(1) Christie SD, Song JK, Fessler RG. Dynamic interspinous process technology. Spine 2005; 30(16 Suppl):S73-S78.

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

(3) Grob D, Benini A, Junge A, Mannion AF. 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 2005; 30(3):324-331.

(4) Kanayama M, Hashimoto T, Shigenobu K, Harada M, Oha F, Ohkoshi Y et al. Adjacent-segment morbidity after Graf ligamentoplasty compared with posterolateral lumbar fusion.[see comment]. Journal of Neurosurgery Spine 2001; 95(1):5-10.

(5) Hashimoto T, Oha F, Shigenobu K, Kanayama M, Harada M, Ohkoshi Y et al. 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 2001; 1(4):283-289.

(6) Rigby MC, Selmon GP, Foy MA, Fogg AJ. Graf ligament stabilisation: mid- to long-term follow-up. Eur Spine J 2001; 10(3):234-236.

(7) Markwalder TM, Wenger M. 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 2003; 145(3):209-214.

Appendix A: Additional papers on non-rigid stabilisation techniques for the treatment of low back pain not included in the summary tables

Article title	Number of patients (n)/ follow-up (FU)	Comments	Direction of conclusions
Caserta S, La Maida GA, Misaggi B et al. (2002) Elastic stabilization alone or combined with rigid fusion in spinal surgery: a biomechanical study and clinical experience based on 82 cases. *Eur Spine J*; 11(Suppl 2):S192–S197.	n = 82 FU = 20 months	Intervention was 'Bronsards' ligament often combined with rigid fusion – results not reported separately	Clinical results 'satisfactory' and reduces stresses on adjacent disc with up to 28 degrees of flexion
Cakir B, Ulmar B, Koepp H et al. (2003) [Posterior dynamic stabilization as an alternative for dorso-ventral fusion in spinal stenosis with degenerative instability]. [German]. *Zeitschrift fur Orthopadie und Ihre Grenzgebiete* 141(4):418–424.	n = 20 (10 dynesys) FU = 15 months	Paper in German journal with English abstract	Oswestry questionnaire scores fell from 46 to 32 points with Dynesys. SF-36 scores improved from 24 to 34, and from 36 to 43 points in physical and mental components, respectively.

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

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

Procedure Number: 306	Procedure name: Flexible stabilisation implants for dynamic lumbar fusion

Action	Comments	Version searched (if applicable)	Date searched
Search for similar NICE topics	IP 100 Prosthetic Intervertebral disc replacement IP 027 Laser Lumbar discectomy IP 191 Interspinous distraction procedures for spinal stenosis	N/A	16.03.05
Consult notification and specialist advisors questionnaires for additional papers	Not available	N/A	15.03.05
Conduct general internet search for background	No information of relevance on this procedure	N/A	15.03.05
Search for Cochrane systematic review	Found 1 cochrane review: Surgery for degenerative lumbar spondylosis	2005 Issue 1	15.03.05
ASERNIP website	Found an accelerated systematic review from Australian Safety and Efficacy Register of New Interventional Procedures - Surgical No. 42 Implantable Spinal Infusion Devices for Chronic Pain and Spasticity	N/A	16.03.05
FDA website	Found report for Dynesys	N/A	16.03.05
Search conferences websites	Found 1. Advanced Techniques in Spinal Decompression & Fixation 2. Spine Surgery: Advanced applications and techniques	N/A	16.03.05
Search Databases:			
Cochrane	23 hits	2005 Issue 1	15.03.05
CRD Databases	11 hits	N/A	17.03.05
EMBase	119 hits	1980 to 2005 Week 11	16.03.05
Medline	118 hits	1966 to March Week 1 2005	16.03.05
Premedline	39 hits	15 March 2005	16.03.05
CINAHL	88 hits	1982 to date	16.03.05
BLIC (limit to current year only)	1 hit	2004 to date	17.03.05
National Research Register	12 hits	2005 Issue 1	16.03.05
Controlled Trials Registry	5 hits	N/A	16.03.05

Database: Cochrane 2005 Issue 1		Date searched: 15.03.05
#1	flexi* near/3 (screw* or implant* or device*) in All Fields in all products	17
#2	rotat* near/3 (screw* or implant* or device*) in All Fields in all products	21
#3	dynesis or dynesys in All Fields in all products	0
#4	dynamic next neutrali*ation next system* in All Fields in all products	0
#5	dynamic near/2 (fus* or stabili*) in All Fields in all products	22
#6	(#1 OR #2 OR #3 OR #4 OR #5)	60
#7	MeSH descriptor Orthopedic Fixation Devices explode all trees in MeSH products	867
#8	MeSH descriptor Arthrodesis explode all trees in MeSH products	263
#9	MeSH descriptor Laminectomy explode all trees in MeSH products	95
#10	MeSH descriptor Lumbar Vertebrae explode all trees with qualifier: SU in MeSH products	210
#11	MeSH descriptor Spinal Fusion explode all trees in MeSH products	238
#12	(#7 OR #8 OR #9 OR #10 OR #11)	1231
#13	flexib* or dynamic or non-rigid or non next rigid in All Fields in all products	4289
#14	(#12 AND #13)	84
#15	(#6 OR #14)	143
#16	MeSH descriptor Spinal Stenosis explode all trees in MeSH products	36
#17	MeSH descriptor Low Back Pain explode all trees in MeSH products	687
#18	MeSH descriptor Spondylolysis explode all trees in MeSH products	4
#19	spondylolisthesis in All Fields in all products	82
#20	lumbar near/3 dis* near/3 disease* in All Fields in all products	49
#21	degenerative next dis* next disease* in All Fields in all products	35
#22	leg next pain* in All Fields in all products	160
#23	back next pain* in All Fields in all products	2201
#24	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23)	2390
#25	(#15 AND #24)	23

Comments: