NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine

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 October 2005.

Procedure name

- Interspinous implants for spinal stenosis.

Specialty societies

- British Orthopaedic association
- Society of British Neurological surgeons
- British Association of Spine Surgeons.
- British Cervical Spine Society.

Description

Indications

Lumbar spinal stenosis is a narrowing of the spinal canal of the low back. Normal wear and tear (degenerative change) 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. It is the most common cause of back-ache but may also, when severe, narrow the spinal canal to pinch the nerve roots.

Unlike disc rupture which can cause sciatica, lumbar spinal canal stenosis does not normally cause pain in the legs at rest. Usually, enough space remains for the nerves to be in a position which the patient finds comfortable most of the time, but

leaning backwards (spinal extension) narrows the canal slightly, and leaning forwards (spinal flexion) enlarges it. Characteristically discomfort in the form of nerve pain, tingling, numbness, or additionally weakness, develops when standing or walking any distance (extension), and is only relieved by sitting or leaning forwards (flexion).

Current treatment and alternatives

Non-operative therapy commonly includes conservative treatment with medication. Nonsteroidal anti-inflammatory medication such as aspirin or ibuprofen may help relieve symptoms. Changes in posture or temporary rest may also help, but because this is a degenerative condition, spontaneous resolution is uncommon, and persistence of symptoms, or progressive reduction of standing time and walking distance is more usually the rule.

When symptoms fail to improve or progress despite conservative treatment, surgery can be performed to decompress the nerve roots by opening the spinal canal and removing the degenerate material (laminectomy). Sometimes when bony instability or severe back pain is an additional issue, these operations may be supplemented by a bony fusion.

This overview provides data on the efficacy and safety of Interspinous implants that have been developed as a less major surgical alternative to spinal decompression. They are placed between adjacent spinous processes to act as a physical block to extension (and thus lumbar canal narrowing) on standing or walking. In this way, and without removing the causative degenerate material, pressure on the nerves may be relieved.

What the procedure involves

Under general or local anaesthesia the patient is positioned with their spine flexed, and the operative level(s) confirmed by X-rays. A midline incision is made over the appropriate spinal levels and deepened to display the spinous processes and their intact joining (interspinous) ligament. The blocking device is sized and positioned in this space between the flexed spinous processes, thus preventing extension during normal activities.

Efficacy

At two years follow up A multi-centre randomised controlled trial comparing interspinous implant to non-operative care of patients with or without back pain but with leg pain relieved by flexion and CT or MRI confirmed spinal stenosis demonstrated a 45% improvement in symptom severity from baseline, compared to a 7% improvement in the control group ($p<0.001$). Physical function scores improved by 44% in patients treated with an implant whereas those treated medically deteriorated by 0.4%($p<0.001$)[2].

A paper providing one year follow up from the same study showed improved QOL outcomes at 6 weeks, 6 months, and 1 year postoperatively[1]. It further showed clinically successful outcomes as demonstrated by improvement in symptom severity and physical function score in 62% of patients treated with an implant compared to 12% who underwent non-operative therapy (these figures are from correspondence with manufacturer). Re-operation was required in 6% (5/88) patients within one year of interspinous implant.

In a case series of patients with mild to moderate stenotic symptoms undergoing interspinous implant insertion, the average operative time was 20 minutes per level

treated 40% (4/10) had an improvement in symptom severity, and 10% (1/10) showed significant improvement in physical function at 11 months post implant [3].

Safety

At one year post implantation the active intervention arm of a RCT found that re-operation was required in 6% (5/88) of patients[1]. A small case series of 10 patients found blood loss to be <100ml in all cases[3].

Intraoperative complication rates among 100 patients undergoing interspinous implant in a randomised controlled trial were 1% (1 case each) for the following complications; respiratory distress, ischemic episode, pulmonary oedema, wound dehiscence, wound swelling, haematoma, and incision pain. At two years follow up there was one incident each of implant misplacement, implant migration, spinous fracture, and increased pain at the implant level[2].

No long-term device durability data are available at present.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to interspinal implants. 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 lumbar/spinal stenosis.
Intervention/test	Flexible interspinal implants that stabilise and support the spine.
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 three papers from two studies; one multi-centre randomised controlled trial (RCT)[1,2], and one small case series[3]. The follow-up time was 24 months for the RCT and a median of 11 months for the uncontrolled study.

Existing reviews on this procedure

There were no systematic reviews or evidence-based guidelines identified for this procedure.

Table 2 Summary of key efficacy and safety findings on interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine

Abbreviations used: NSAID, non-steroidal anti-inflammatory drug; MRI, magnetic resonance imaging; LSS, lumbar spinal stenosis; SSS, Swiss Spinal Stenosis questionnaire; ODI, Oswestry Disability Index; ITT, intention to treat.

Study details	Key efficacy findings	Key safety findings	Comments
Zucherman JF, (2004)[1] Randomised controlled trial USA 9 study sites n=200 subjects recruited 100 received X-Stop intervention 91 non-operative care (nine broke randomisation after selection to non-operative care group) Patients in the non-operative group received at least one epidural steroid injection and could receive NSAIDs, analgesics, and physical therapy Patients 50+ years, leg, buttock or groin pain (with or without back pain) that was relieved during flexion. Stenosis was confirmed by CT or MRI scans Analysis using ANOVA for SF036 and by Fisher exact test for ZCQ. Significant differences are determined at $p < 0.05$ Data collected at baseline, 6 weeks, 6 months, and 1 year. Results presented here for 1 year follow-up unless stated There were no statistical differences at baseline between the study arms in terms of age, height, weight, symptom severity scores, or physical function	**The medical outcomes short form-36 (SF-36)** At the 6-week, 6-month, and 1-year follow-up points the X-Stop group scored significantly better than the non-operative group in every domain (absolute values not presented) These scores were also significantly better than at baseline at each time point and in every domain **The Zurich Claudication Questionnaire (ZCQ)** A validated tool that captures patient data in three domains: symptom severity, physical function, and post-treatment patient satisfaction. Treatment is considered successful if the patient is at least 'somewhat satisfied' and has at least a 0.5 score improvement in both symptom severity and physical function At 1 year the physical function domain was improved in 67.4% of the X-Stop patients and 18.8% of non-operative patients, a significant improvement* At 1 year the symptom severity score was significantly improved among the X-Stop patients with 73.1% noting improvements compared with 22.1% of non-operative patients* Clinical success on the ZCQ scale is determined by a significant improvement in both symptom severity and physical function, and be satisfied with the treatment outcome. This analysis showed a success rate of 62.0% in the X-Stop arm which was significantly higher than the 11.6% in the non-operative arm* * denotes values provided through correspondence with manufacturer	Re-operation rate 6% (5/88) No other side-effects or complications recorded	Not clear whether analysis undertaken on ITT principle, although patients who had the implant removed, formally withdrew from the study or underwent a laminectomy were considered failures in the X-Stop group. 88% (88/100) of patients in the X-Stop arm and 75% (68/91) in the non-op arm were followed up to 1 year. Randomisation by block allocation at each centre. No details of blinding or concealment. For ZCQ results are presented as an improvement rate, rather than a raw score. No direct comparison to other surgical procedures. A systematic review of 74 studies for surgery for lumbar spinal stenosis found good to excellent outcomes in 64% cases in first year; however, population characteristics may not be comparable.

Abbreviations used: NSAID, non-steroidal anti-inflammatory drug; MRI, magnetic resonance imaging; LSS, lumbar spinal stenosis; SSS, Swiss Spinal Stenosis questionnaire; ODI, Oswestry Disability Index; ITT, intention to treat.

Study details	Key efficacy findings	Key safety findings	Comments
Zucherman JF, (2005)[2] n = 174 (93 X-STOP) Details as above Follow-up = 2 years	**The Zurich Claudication Questionnaire (ZCQ)** Changes from baseline at 2 years follow up **X-Stop** / **Control** / **p** Symptom severity: 45.4% / 7.4% / < 0.001 Physical function: 44.3% / –0.4% / < 0.001 60% (56/93) of patients in the X-Stop group demonstrated a clinically significant improvement in symptom severity compared with 19% (15/81) of patients in the control group (p < 0.001) In the X-STOP group 48% of patients fulfilled all three ZCQ criteria compared with 5% of the control group **Predictors of outcome** A positive femoral stretch test at baseline (p = 0.010), no comorbidity (p = 0.013), and low surgical blood loss during the procedure (p = 0.007) were the only independent predictors of a positive treatment outcome in multivariate analysis **Additional surgery** 6% (6/93) of the X-Stop group and 30% (24/81) of the control group required laminectomy for unresolved symptoms in the 2-year follow-up period Comparison of outcomes between the X-stop group and the 24 patients in the control group who went on to have a laminectomy showed no significant difference in the main clinical outcomes No X-Stop implantation procedures were converted to a laminectomy, during the procedure	**Complications** **Complication** / **X-Stop** / **Control** *Intraoperative* Respiratory distress: 1% (1/100) / 0% Ischemic episode: 1% (1/100) / 0% Pulmonary oedema: 1% (1/100) / 0% Wound dehiscence: 1% (1/100) / N/A Wound swelling: 1% (1/100) / N/A Haematoma: 1% (1/100) / N/A Incision pain: 1% (1/100) / N/A Injection intolerance: N/A / 1% (1/91) Symptom flare: N/A / 1% (1/91) Leg paresthesia: N/A / 2% (2/91) Increased back pain: N/A / 1% (1/91) Heart attack: N/A / 1% (1/91) *Device related* Malpositioned implant: 1% (1/100) / N/A Implant migration: 1% (1/100) / N/A Spinous fracture: 1% (1/100) / N/A Increased pain at implant level: 1% (1/100) / N/A	From original X-Stop treatment group 7 patients were lost to follow-up: 4 died, 2 failed to complete outcome questionnaire, and 1 withdrew. From the control group 10 patients were lost to follow-up: 3 died, 1 could not tolerate epidural and 6 withdrew. These patients were not included in analysis. Block randomisation by study centre. Radiographic assessment undertaken by an independent physician. Not stated how many cases obtained from each participating centre, potential for learning curve to affect outcomes if few procedures undertaken. A highly selected study population with exclusion of cases with spondylolisthesis of greater than grade 1 on a 1–4 scale

Abbreviations used: NSAID, non-steroidal anti-inflammatory drug; MRI, magnetic resonance imaging; LSS, lumbar spinal stenosis; SSS, Swiss Spinal Stenosis questionnaire; ODI, Oswestry Disability Index; ITT, intention to treat.

Study details	Key efficacy findings	Key safety findings	Comments
Lee J, (2004)[3] Case series X-Stop interspinous implant July 2001 to April 2002 Japan 10 patients Patients 60+ years, mild to moderate stenotic symptoms, pain relieved when flexed and aggravated when extended, dural sac compression in extension confirmed on MRI. Exclusion criteria included unremitting pain in any position, fixed motor deficit, severe LSS at 3+ levels, spinal instability General anaesthesia, a midline skin incision of 5 cm above the spinal processes of the stenotic level, para spinal muscle was elevated to the level of the facets and laminae. Operative level verified by fluoroscopy, and X-Stop inserted from the right side as close to the laminae as possible Mean age = 71 years (range 61–79 years), Male = 70%, spinal claudication in seven patient s Surgical and postoperative complications reviewed, patient satisfaction rating, and the validated SSS employed for clinical outcomes. Also MRI-derived dimensions of dural sac and intervertebral foramina recorded (data not presented here) Follow-up(mean): 11 months	**SSS outcomes** 70% (7/10) of the patients were at least somewhat satisfied with the outcome 40% (4/10) of patients had a significant improvement in symptom severity (postoperative average score minus preoperative score ≥ 0.5) 10% (1/10) of patients showed a significant improvement in physical function	Average operative time was 20 minutes/level . Blood loss < 100 ml No intraoperative complications such as implant failure, bony failure, or infection	A highly selective cohort was used in this study with moderate but not severe pain. A self-reported outcome used SSS, with potential Hawthorne effect being recorded. Relatively short follow-up may have been insufficient to assess technical failure of device. Complete decompression may not be necessary to achieve symptomatic relief. Paired t-test used for analysis with significance assumed at $p < 0.05$

Validity and generalisability of the studies

- Studies had carefully selected patient cohorts and included only patients for whom pain relief at baseline was achieved in flexion but exacerbated in extension.
- All efficacy outcomes were subjective self-reported scales.
- No follow-up was longer than 2 years.
- Some participating centres may not have completed many device implantation procedures, and no intercentre analysis was performed.

Specialist Advisors' opinions

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

- Advisors suggested that it is unclear whether this procedure falls within the realm of neurosurgery or orthopaedics.
- It is likely that this procedure will be available at a moderate number of NHS sites, although the impact on the NHS is thought to be minor because only a fraction of patients who are currently treated by decompression would be suitable for the procedure.
- There are concerns about additional pain in adjacent levels, device migration, and potential infection, although the required incision is smaller than for surgical decompression.
- It is uncertain whether the implants can be safely removed, but for some devices the presence of the implant is not thought to hamper laminectomy.
- Advisors commented that, given fluctuating symptoms in this condition, outcome assessment of clinical studies may be unreliable.
- Some advisors questioned the long-term efficacy of the procedure.

Issues for consideration by IPAC

- Implant systems may fail in the long term but may be a useful alternative to decompressive spinal surgery in the unfit, the frail, or those who choose the less major procedure.
- Potential for spread of segment degeneration through segmental creep, with potential additional stresses to non-stabilised areas, needs to be balanced against the natural progression of the disease.

References

1 Zucherman JF, Hsu KY, Hartjen CA et al. (2004) A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. *European Spine Journal* 13(1):22–31.

2 Zucherman JF, Hsu KY, Hartjen CA et al. (2005) A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine* 30(12):1351–8.

3 Lee J, Hida K, Seki T et al. (2004) An interspinous process distractor (X STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases. *Journal of Spinal Disorders & Techniques* 17(1):72–7.

Appendix A: Additional papers on interspinous implants for spinal stenosis not included in the summary tables

Article title	Number of patients/follow-up	Comments	Direction of conclusions
Whitesides TE Jr.(2003) The effect of an interspinous implant on intervertebral disc pressures. *Spine* 28(16):1906–8)	N/A	Letter	History of implant development
Lindsey DP, Swanson KE, Fuchs P et al. (2003) The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. *Spine* 28(19):2192–7.	N/A	In vitro study	X-Stop device in cadaveric spines did not significantly reduce flexion-extension range of adjacent segments

Appendix B: Literature search for interspinous implants for spinal stenosis

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.

#	Search History	Results	Display
1	spin$.mp. [mp=ti, ot, ab, rw, sh] Details	260938	Display
2	implant.mp. [mp=ti, ot, ab, rw, sh] Details	33218	Display
3	exten$.mp. [mp=ti, ot, ab, rw, sh] Details	540711	Display
4	Spinal Stenosis/co, pa, pp, su, th [Complications, Pathology, Physiopathology, Surgery, Therapy] Details	1574	Display
5	limit 4 to human [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained] Details	1524	Display
6	neurogen$.mp. [mp=ti, ot, ab, rw, sh] Details	17271	Display
7	device.mp. [mp=ti, ot, ab, rw, sh] Details	59535	Display
8	stop.mp. [mp=ti, ot, ab, rw, sh] Details	20620	Display
9	pain.mp. [mp=ti, ot, ab, rw, sh] Details	208800	Display
10	back.mp. [mp=ti, ot, ab, rw, sh] Details	60469	Display
11	vertibr$.mp. [mp=ti, ot, ab, rw, sh] Details	7	Display
12	cludication.mp. [mp=ti, ot, ab, rw, sh] Details	0	-
13	1 or 10 or 11 Details	313051	Display
14	2 or 7 or 8 Details	111097	Display
15	6 or 9 Details	225020	Display
16	5 and 13 and 14 and 15 Details	9	Display
17	5 and 13 and 14 Details	33	Display