NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

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

Lumbar spinal stenosis is a narrowing of the spinal canal in the lower part of the back. This causes discomfort in the legs when standing or walking because of pressure on the spinal nerves. This procedure involves implanting a device into the space between two back bones to relieve pressure on the nerves and, therefore, pain in the legs.

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 April 2010.

Procedure name

- Interspinous distraction procedures
- Interspinous process distraction
- Interspinous process decompression (IPD)
- Insertion of interspinous implants/spacers

Specialty societies

- British Association of Spinal Surgeons (BASS)
- Society of British Neurological Surgeons (SBNS)
- British Orthopaedic Association (BOA)

Description

Indications and current treatment

Wear and tear of the spinal column causes loss of height in the discs with consequent bulging of discs, enlargement of facet joints, overgrowth of the ligamentum flavum and narrowing of the spinal canal. When severe, the nerves of the cauda equina may be pinched by ligamental inbuckling when the spine is lordosed (extended). This principally causes leg pain when standing or walking and is relieved when flexing the spine by sitting or bending to stretch the ligamentum and open the canal.

Conservative treatment with non-steroidal anti-inflammatory medication, postural changes or temporary rest may help relieve symptoms. However, because this is a degenerative condition, spontaneous resolution is uncommon.

When symptoms persist, surgery is sometimes performed to decompress the spinal nerve roots by removing the degenerate material (laminectomy or ligamentectomy). Sometimes when bony instability or severe back pain is an additional issue, decompression surgery may be supplemented by fusion or dynamic stabilisation.

What the procedure involves

The potential advantage of interspinous distraction procedures is that they are less invasive compared with decompressive surgery. The aim of the procedures is to relieve stenosis and pressure on the spinal nerves by placing an implant between the spinous processes of the affected joints (usually L4/5 vertebrae, but sometimes others or more than one). These implants inhibit spinal extension, with the intention of preventing or reducing leg pain when standing or walking.

These procedures are normally carried out with the patient under local anaesthesia and conscious sedation, but general anaesthesia may be used. The patient is positioned with their spine flexed: operative level(s) are usually confirmed by fluoroscopy. The vertebral spinous processes and their interspinous ligament are exposed through a midline incision. An implant of appropriate size is positioned through the supraspinous ligament, which helps to hold the implant in place between the flexed spinous processes of adjacent vertebrae. More than one spacer may be inserted for multiple level disease.

Instruments used to assess efficacy

The Oswestry Disability Index (ODI) is a validated, patient-completed questionnaire used to assess 10 parameters: 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.

The Zurich Claudication Questionnaire (ZCQ) is a validated, patient-completed tool that captures patient data in three domains: symptom severity, physical function and post-treatment patient satisfaction.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. Searches were conducted of the following databases, covering the period from their commencement to 30 July 2010: 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. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. 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 lumber spinal stenosis causing neurogenic claudication.
Intervention/test	Interspinous distraction procedures.
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 approximately 937 patients from 1 randomised controlled trial (RCT) (including an additional publication based on a subset of the patients in this RCT), 3 non randomised studies, 6 case series, 1 case series published as an abstract, and 2 case reports.

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 interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details

Zucherman JF (2005)[1], Hsu KY (2006)[2]

(Zucherman JF (2005)[1] in previous overview)

RCT

USA

Recruitment period: 2000 – 2001

Study population: patients with leg, buttock or groin pain (with or without back pain) which was relieved during flexion and stenosis confirmed by CT or MRI.

n = **191 (100 interspinous process decompression [136 levels] vs. 91 conservative management)**

Age: 70 vs. 69 years

Sex: not reported

Patient selection criteria: 50+ years old, ability to walk at least 50 feet

Exclusion criteria: fixed motor deficient, cauda-equina syndrome, previous

Key efficacy findings

Number of patients analysed: **174 (93 interspinous process decompression vs. 81 conservative management)**

Of those treated with X-STOP, most were treated at level L4/L5 (89) and some at L3/L4 (43); only 4 required hospital stay > 24 hours.

ZCQ[1]

		ZCQ domain	
		Symptom severity	**Physical function**
Average % improvement from baseline to 2 years	X-STOP	45.4%	44.3%
	control	7.4%	–0.4%
No. of patients with clinically significant improvement at 2 years	X-STOP	60.2% (56/93)	57% (53/93)
	control	18.5% (15/81)	14.8% (12/81)

(p < 0.001 between groups for all comparisons; results consistent at all follow-up periods [including earlier follow-up periods with fewer patients lost to follow-up]; difference in improvement between follow-up periods within each group not significant; analysis includes 28 patients treated with laminectomy for persistent stenosis symptoms in the follow-up period [X-STOP: 6, control: 24]).

	% of patients satisfying all 3 areas of ZCQ
X-STOP	48.4% (45/93)
control	4.9% (4/81)*

*exact numbers not reported so calculated by IP analyst; not significant between laminectomy and X-STOP (not reported between other comparisons)

Conversion to laminectomy

6% (6/100) of patients from the X-STOP group and 26% (24/91) from control

Key safety findings

Deaths

One patient with a history of cardiovascular disease developed pulmonary oedema 2 days after the device implantation and subsequently died.

Complications

Complication	X-STOP	Control
Intraoperative		
Respiratory distress	1% (1/100)	0%
Ischemic episode without sequelae	1% (1/100)	0%
Wound dehiscence	1% (1/100)	NA
Wound swelling	1% (1/100)	NA
Haematoma	1% (1/100)	NA
Incision pain	1% (1/100)	NA
Injection intolerance	NA	1% (1/91)
Symptom flare requiring overnight hospital stay	NA	1% (1/91)
Leg paresthesia	NA	2% (2/91)
Postoperative		
Increased back pain after 6 hours	NA	1% (1/91)
Heart attack after 3 days	NA	1% (1/91)
Device related		

Comments

Follow-up issues:

- Data collected at 6 weeks, 6 months, 1 and 2 years.
- Loss to follow-up: 7 patients treated with X-STOP (4 died, 2 failed to complete outcome questionnaire, and 1 withdrew), 10 patients in the control group (3 died, 1 could not tolerate epidural and 6 withdrew) (all 7 deaths were unrelated to treatment).

Study design issues:

- 9 study sites with block randomisation by centre (both publications reporting outcomes on same group of patients).
- No details of blinding.
- Patient recruitment

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details

lumbar surgery at the stenotic level, spondylolisthesis at a grade greater than I at the affected level (scale I to IV).

Technique: intervention – fluoroscopy to determine location before X-STOP (St. Francis Medical Technologies, Inc, CA, USA) insertion (usually with local anaesthetic); control – epidural steroid injection followed by prescription of additional injections, NSAIDs, analgesics and physical therapy, as necessary.

Follow-up: **2 years**

Conflict of interest/source of funding: funded by manufacturer

Key efficacy findings

group underwent laminectomy because of unresolved stenosis symptoms during the 2-year follow-up (total of 30 had laminectomy).

Of the 28 patients with outcomes available after laminectomy, 42.9% (12/28) satisfied all areas of the ZCQ (not clear which group these 12 patients were in).

Health-related quality of life[2] (as measured from the SF-36 questionnaire with score 0–100)

Domain	X-STOP		Control	
	Preop	2 yrs	Preop	2 yrs
Physical function [a]	31.7	59.3	33.9	41.4
Reduction in health-related physical limitations [a]	13.5	51.4	19.5	28.2
Reduction in bodily pain [a]	24.5	53.8	27.4	34.5
General health	70.2	69.9	67.6	64.5
Vitality (energy levels) [b]	45.2	58.3	42.9	49.7
Social functioning [b]	58.8	81.2	64.3	70.4
Reduction in emotional problems	52	73.4	52.2	61.7
Mental health [b]	74.8	79.7	72.4	73.2
PCS [a]	27.8	38.4	28.9	31.2
MCS	51.5	54.3	50.6	52.5

Differences between groups were significant at 2 years for all domains except emotional problems, general health and MCS (a: $p \leq 0.001$ and b: $p < 0.03$).

Radiographic assessment: There was no change in the distance between spinous processes in 96% of patients from 6 weeks to 2 years (exact numbers not reported).

Key safety findings

Malpositioned implant	1% (1/100)	NA
Implant migration after fall*	1% (1/100)	NA
Spinous process fracture**	1% (1/100)	NA
Increased pain at implant level***	1% (1/100)	NA

*time of occurrence not reported; removed without sequelae (not further described)
**detected on 6 month radiograph; no more treatment required (not further described)
***after 382 days (not further described)

Comments

not described.

- Patients 'lost to follow-up' not included in analysis but those converted to laminectomy because of unresolved stenosis were (X-STOP: 6% [6/100], control: 26% [24/91]).
- Radiographic assessment 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.

Study population issues:

- No significant difference between groups in preoperative characteristics (including age, presence of

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
			spondylolisthesis [35% and 27% of patients, respectively], in baseline SF-36 score or ZCQ symptom severity or physical function domain scores). • Treatment protocol for control group not standardised. • Univariate analysis showed presence of spondylolisthesis not predictive of outcomes (clinical success in 55.9% [19/34] with spondylolisthesis and 44.1% [26/59] without).

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details

Anderson PA (2006)[3]

RCT

USA

Recruitment period: not reported

Study population: patients with LSS associated with lumbar degenerative spondylolisthesis

n = **75 (42 interspinous decompression vs. 33 conservative treatment)**

Mean age: 71.4 vs. 68.5 years

Sex: 54.8% vs. 66.7% female

Symptoms lasting > 2 years: 64.3% vs. 63.6%

Patient selection criteria: at least 50 years old with symptom relief on sitting or flexion, at least 6 months of non-operative treatment

Exclusion criteria: inability to walk at least 50 feet and/or inability to sit for at least 50 minutes or if anterior translation greater than 25% on imaging, history of osteoporotic fracture

Key efficacy findings

Number of patients analysed: **75 (42 interspinous decompression vs. 33 conservative treatment)**

ZCQ

Symptom severity and physical function scores were combined into a scale of 0 to 100 with 100 representing worst disability.

Post-treatment patient satisfaction was measured with a questionnaire scoring 0 to 5 with 0 being greatest satisfied

Mean figures are as follows

ZCQ scoring	Follow-up	X-STOP	Control
Symptom and function	Baseline	50.40 ± 2.04	51.26 ± 2.39
	2 years	23.05 ± 3.14	47.40 ± 3.18
Patient satisfaction	After treatment	1.55 ± 0.11	2.80 ± 0.18

± denotes standard error of the mean

Statistically significant difference between X-STOP and control ($p < 0.0001$), from baseline to follow- up for X-STOP and in patient satisfaction (p value not reported for last 2).

Health-related quality of life (as measured from the SF-36 questionnaire with score 0–100)

SF-36 domain summary	Follow-up	X-STOP	Control
PCS	Baseline	31.53 ± 1.68	28.19 ± 1.29
	2 years	41.19 ± 1.97	28.14 ± 1.10
MCS	Baseline	52.06 ± 1.76	49.92 ± 1.78
	2 years	56.29 ± 1.25	49.66 ± 2.22

Key safety findings

Complications

Complication	X-STOP (No.)	Control
Incisional complication resolved after 1 week of oral antibiotic therapy	2.4% (1/42)	0
Malpositioned implant later detected on radiographic examination	2.4% (1/42)	0
Reaction to epidural steroid injection	NA	3% (1/33)

(percentages calculated by IP analyst)

Comments

Patients included in Zucherman 2005

Follow-up issues:

- At 6 weeks, 6, 12 and 24 months.
- At 2 years, 93.3% (70/75) of patients were available for follow-up (this was reported to be 98.9% of intervention and 92.1% of control group but it is not clear how many patients were from each group).

Study design issues:

- This is a cohort of 75 patients with degenerative spondylolisthesis from Zucherman JF (2005). It was defined as 5─25% anterior translation on standing lateral radiograph.
- Treatment protocol for control group not standardised.
- Continuous variables of the patients who

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Technique: intervention – fluoroscopy to determine location before X-STOP (St. Francis Medical Technologies, Inc, CA, USA) insertion (under local anaesthetic), control – epidural steroid injection followed by prescription of additional injections, NSAIDs, analgesics and physical therapy, as necessary. Follow-up: **2 years** Conflict of interest/source of funding: primary author is a consultant for and stockholder for the manufacturer	Statistically significant difference in PCS between baseline and 2 year figures for X-STOP group (p value not reported). Neither group had significantly different MCS than normal asymptomatic individuals. ***Additional surgery*** 9 patients were treated with laminectomy or laminectomy and fusion (5 in X-STOP group and 4 in control group) ***Radiographic assessment*** There was no statistically significant change in the percentage of spondylolisthesis and kyphotic angulation at baseline and 2 years.		converted to laminectomy (5 X-STOP, 4 control) were included in ITT analysis. **Study population issues**: • No significant differences in preoperative characteristics including SF-36 score or severity of ZCQ.

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Park S (2009)[4]
Non-randomised comparative study
Korea
Recruitment period: 2003 – 2005
Study population: patients with degenerative LSS with neurogenic claudication
n = 61 (30 interspinous spacer vs. 31 PLIF)
Mean age: 66.2 years and 60.4 years
Sex: 43% and 61.3% female

Patient selection criteria: symptomatic (low back pain, radiating pain and neurogenic claudication), medically intractable LSS with or without degenerative spondylolisthesis grade 1 who completed at least 2 years of follow-up; also refractory to analgesics, physiotherapy or caudal epidural block
Exclusion criteria: prior surgical treatment, trauma, infection, any other spinal disease like ankylosing spondylitis and pathological fracture, degenerative</td>
<td>Number of patients analysed: 61 (30 interspinous spacer vs. 31 posterior lumbar interbody fusion)

Pain resolution (VAS) and disability (ODI)
These were inquired and collected by telephone interview at final follow-up (mean 40.4 months for intervention group and 38.4 months for the control group). VAS scale was not described but appears to be on a scale of 0 to 10 with 10 being the worst pain.
<table>
<tr><th></th><th>Follow-up</th><th>Coflex</th><th>PLIF</th></tr>
<tr><td rowspan="2">VAS low back pain</td><td>Baseline</td><td>4.7 ± 2.0</td><td>5.5 ± 2.6</td></tr>
<tr><td>Follow-up</td><td>2.4 ± 1.7</td><td>3.3 ± 2.0</td></tr>
<tr><td rowspan="2">VAS leg pain</td><td>Baseline</td><td>6.9 ± 1.7</td><td>6.5 ± 2.4</td></tr>
<tr><td>Follow-up</td><td>2.4 ± 2.0</td><td>2.6 ± 2.1</td></tr>
<tr><td rowspan="2">ODI*</td><td>Baseline</td><td>23.0 ± 8.5%</td><td>20.5 ± 7.4%</td></tr>
<tr><td>Follow-up</td><td>11.3 ± 9.4%</td><td>10.9 ± 7.6%</td></tr>
</table>
* units added by analyst (not reported in study)
p < 0.001 from baseline to follow-up for all scores
The only statistically significant difference between groups is low back pain on VAS at baseline (p = 0.036).

Radiological assessment in disk-height ratio
Both groups had significantly increase in postoperative disk height (intervention: 18.6, p = 0.002 and control: 15.8, p = 0.001) but disk height was still significantly lower in the control group than the intervention group (as it was preoperatively). However, at the last follow-up (mean 40.4 months for intervention and 38.4 months for control), the disk height that had been resolved was lost in comparison with the postoperative value (p = 0.027).

In patients with degenerative spondylolisthesis, change in vertebral slip
Vertebral slip was reduced in both groups but was lower in the intervention group</td>
<td>Complications
<table>
<tr><th>Complication</th><th>X-STOP (No.)</th><th>PLIF</th></tr>
<tr><td>Fractured interspinous spacer*</td><td>3.3% (1/30)</td><td>N/a</td></tr>
<tr><td>Compression of operation site by bony materials between nerve root and implant requiring reoperation**</td><td>3.3% (1/30)</td><td>N/a</td></tr>
<tr><td>Infection and screw malposition, respectively, requiring reoperation**</td><td>0</td><td>6.5% (2/31)</td></tr>
<tr><td>Radiolucent gaps between implant and spinous process****</td><td>57% of patients followed up radiologically over 24 months***</td><td>0</td></tr>
</table>
Percentages calculated by IP analyst.
*no other details such as time of occurrence or sequelae described
**time of occurrence not reported
***exact number of patients not reported
****no information offered in the study about the potential clinical importance of this finding.</td>
<td>Follow-up issues:
Arrangements for follow-up not well described. Radiographs were taken at baseline, postoperatively and at final follow-up. Surveys were taken at baseline and then by telephone at final follow-up.
No reported loss to follow-up.
Study design issues:
Retrospective study of consecutive series.
VAS was not described by the study.
Study population issues:
Patients in the intervention group were older (p = 0.003), had less low back pain at baseline (p = 0.036), had greater disk height (p = 0.016), had</td>
</tr>
</table>

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
spondylolisthesis greater than grade II, isthmic spondylolisthesis, cauda equina syndrome, patients also having instrumented fusion Technique: intervention – use of Coflex (Paradigm Spine inc®, USA) implant (anaesthetic not described), comparator – PLIF with total laminectomy and partial or total facetectomy for decompression Maximum follow-up: **51 months (intervention) and 54 months (control)** Conflict of interest/source of funding: not reported	(though this was not significant. At the final follow-up, vertebral slip in the intervention group increased significantly (p = 0.04; there was no significant change in the control group).		lower mean vertebral slip (not significant) and had significantly different numbers of operated levels (intervention: 26 treated at one level, 4 at 2 levels and none at 3 levels; these figures were 15, 15 and 1, respectively, for the control group; p < 0.001). • Degenerative spondylolisthesis associated with 12 levels in the intervention group and 9 in the control group. Its presence did not influence VAS or ODI scores in the intervention group.

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

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<tr>
<td>Richter A (2010)[14]

Non-randomised comparative study
Germany
Recruitment period: 2006 – 2007
Study population: MRI-confirmed findings of LSS and minimum 3 months of failure of conservative treatment
n = 60 (30 with decompression and interspinous implant vs 30 with decompression)
Mean age: 68.3 and 68 years
Sex: 47% and 40% female

Patient selection criteria: clinical and radiographic criteria of symptomatic LSS, 1 or 2 level stenosis, between 45 and 80 (including grade 1 degenerative spondylolisthesis)
Exclusion criteria: isthmic spondylolisthesis, lesions at more than 2 levels, previous lumbar spine surgery,</td>
<td>Number of patients analysed: 60 (30 with decompression and interspinous implant vs 30 with decompression)

ODI
<table><tr><th>Group</th><th>Baseline</th><th>Post operative</th><th>12 months</th></tr><tr><td>Intervention</td><td>48</td><td>35</td><td>18</td></tr><tr><td>Control</td><td>38</td><td>20</td><td>19</td></tr></table>(values estimated by analyst from figures)

Scores improved over time in all groups ($p < 0.001$), but there was no significant difference between the groups ($p = 0.22$).

Roland-Morris disability questionnaire
All patients had a significant difference in this questionnaire over time but there was no significant difference between the groups.

VAS
All patients improved significantly over time ($p < 0.001$) but there was no significant difference between groups.

Walking distance
All patients improved significantly in walking distance over time ($p < 0.001$) but there were no significant differences between groups.

Patient satisfaction
There was no significant difference between the groups.

Revisions
Two patients required revisions with pedicle screw fusion of the segment (timing and reason for revision not reported).</td>
<td>Complications
One patient treated with the device had a dislocated implant because of spinous process fracture requiring fusion.

One patient in the control group had to be ‘instrumented and fused’ (it is not clear what this means).

Both groups had a case of CSF leak (subsequent treatment and sequelae not described).</td>
<td>Follow-up issues:
• Patients followed up at 3, 6 and 12 months.

Study design issues:
• Roland-Morris disability questionnaire and VAS not described.
• Values for scores other than ODI were difficult to extract from the figures.

Study population issues:
• No significant differences in demographics between groups except intervention group had slightly higher ODI over time before the procedure ($p < 0.001$).
• Degenerative spondylolisthesis associated with 11 in intervention and 18 in control group</td>
</tr>
</table>

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
segmental instability. Technique: under general anaesthetic, patients treated with posterior decompression involving partial laminectomy, intervention group then received: Coflex (Paradigm Spine) at 1 or 2 levels. Follow-up: **1 year** Conflict of interest/source of funding: not reported			

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

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<tr>
<td>Kong (2007)[5]

Non-randomised comparative study
Korea
Recruitment period: 2000 – 2003
Study population: degenerative spinal stenosis with degenerative spondylolisthesis (Grade 1) or mild angular instability at L4/L5
n = 42 (18 interspinous implantation vs. 24 PLIF)
Mean age: 61.7 and 56 years
Sex: 83% and 67% female

Exclusion criteria: marked degenerative spondylolisthesis, lesions at more than 2 levels, isthmic spondylolisthesis

Technique: both procedures under general anaesthetic, intervention: Coflex (Spine Motion, Germany) – comparator, – PLIF with Poly-ether-ether-ketone (Stryker Implants, France) or</td>
<td>Number of patients analysed: 42 (18 interspinous implantation vs. 24 PLIF)

Pain resolution (VAS) and disability (ODI)
The VAS scale was not described. From a bar graph it appears to be 0–9 or 0–10.
<table>
<tr><th></th><th>Follow-up</th><th>Coflex</th><th>PLIF</th></tr>
<tr><td rowspan="2">VAS low back pain</td><td>Baseline</td><td>7.4</td><td>7.9</td></tr>
<tr><td>Follow-up</td><td>3.2</td><td>3.0</td></tr>
<tr><td rowspan="2">VAS lower leg pain</td><td>Baseline</td><td>8.1</td><td>7.6</td></tr>
<tr><td>Follow-up</td><td>2.9</td><td>2.4</td></tr>
<tr><td rowspan="2">ODI</td><td>Baseline</td><td>55%</td><td>60%</td></tr>
<tr><td>Follow-up</td><td>28%</td><td>25%</td></tr>
</table>
(values were estimated by the analyst from bar graphs; $p < 0.05$ from baseline to follow-up for each outcome but differences between groups were not significant)
Range of motion (ROM)
<table>
<tr><th></th><th colspan="2">Coflex</th><th colspan="2">PLIF</th></tr>
<tr><td></td><td>Baseline degree of ROM</td><td>degree of ROM at 1 year</td><td>Baseline degree of ROM</td><td>degree of ROM at 1 year</td></tr>
<tr><td>L3/4</td><td>6.1 (±3.7)</td><td>5.8 (±3.8)</td><td>7.2 (±4.1)</td><td>10.5 (±5.2)</td></tr>
<tr><td>L4/5</td><td>10.0 (±4.1)</td><td>5.1 (±4.8)</td><td>12.7 (±3.7)</td><td>0.7 (±1.5)</td></tr>
<tr><td>L5/S1</td><td>6.6 (±4.8)</td><td>5.1 (±4.8)</td><td>11.2 (±5.8)</td><td>10.2 (±7.6)</td></tr>
<tr><td>Posterior disk height</td><td>7.8 (±1.8)</td><td>9.1 (±2.2)</td><td>6.9 (±2.9)</td><td>11.2 (±1.3)</td></tr>
</table>
($p < 0.05$ from baseline to follow-up for each outcome but differences between groups were not significant)</td>
<td>Complications
There were no surgical complications in either group.</td>
<td>Follow-up issues:
• Patients followed up at outpatient clinic at 1, 3, 6 and 12 months.

Study design issues:
• Consecutive patients
• Retrospective

Study population issues:
• No significant differences in demographics between groups.</td>
</tr>
</table>

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
CH cage (Spine-Tech, USA) plus pedicle screw fixation Follow-up: **1 year** Conflict of interest/source of funding: supported by grant from IN-SUNG Foundation for Medical Research			

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kuchta J (2009)[6]

Case series
Germany
Recruitment period: 2003 – 2007
Study population: neurologic intermittent claudication due to LSS confirmed on MRI
n = 175 (184 implantations)
Mean age: 69.4 years
Sex: 38% female

Patient selection criteria: radiating leg/buttock/grain pain with or without back pain, no previous fusion or laminectomy, positional claudication with relieve of symptoms in flexion, refractory to conservative treatment over 6 months
Exclusion criteria: titanium allergy, severe osteoporosis, cauda equine, > grade 1 spondylolisthesis, severe scoliosis, ankylosis at affected level, acute fracture of spinous processes or pars interarticularis, systematic infection at time of surgery</td>
<td>Number of patients analysed: 175

112 were treated at L4/L5, 47 at L3/L4, 13 L2/L3, 2 L1/2, 6 L5/S1

Pain resolution (VAS) and disability (ODI)

VAS scales were not described but it appears to be on a scale of 0 to 100 with 0 being worst pain.
<table>
<tr><th></th><th>Mean preoperative score (range, SD)</th><th>Mean postoperative score (range, SD)</th><th>Mean 24 month score (range, SD)</th></tr>
<tr><td>VAS (leg pain)</td><td>61.1 (20–100, 29.8)</td><td>38.9 (0–100, 39.0)</td><td>39.0 (0–75, 28.3)</td></tr>
<tr><td>ODI</td><td>32.6% (8–80, 16.0)</td><td>22.7% (0–85, 15.6)</td><td>20.3% (0–42, 17.5)</td></tr>
</table>
(The drop in VAS preoperatively to postoperatively was significant, $p < 0.005$ and remained stable throughout follow-up of 2 years; significance not reported for ODI scores)

Revisions
4.6% (8/175) of patients required removal of X-STOP followed by microsurgical decompression because of unsatisfactory effect of the procedure (no more details such as timing was provided).</td>
<td>Complications
There were no complications reported in this study.</td>
<td>Follow-up issues:
• Patients were followed up at 6 weeks, 6 months and 1 and 2 years.
• No reported loss to follow-up.

Study population issues:
• Unlike most studies in this overview, there are more males than females in this study. Male patients had a significantly lower VAS both before and after the operation (and a lower ODI score preoperatively).
• There was no significant difference in ODI or VAS in patients with symptoms at different levels.
• Number of patients with degenerative spondylolisthesis not reported.</td>
</tr>
</table>

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Technique: target level confirmed with fluoroscopy before implantation with X-STOP (St. Francis Medical Technologies, Inc, CA) (use of anaesthetic not reported) Maximum follow-up: **4 years** Conflict of interest/source of funding: not reported			

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
Senegas J (2007)[12] **Case series** France Recruitment period: 1987–1995 Study population: patients with symptomatic degenerative instability initially scheduled for fusion n = **241** Age: 46.9 years (mean) Sex: 73.9% (105/142) male Patient selection criteria: devices inserted after decompressive procedures for isolated canal stenosis, recurrent disc herniation, massive primary disc herniation, or canal stenosis decompensated by primary or recurrent herniated discs. Technique: single or multilevel interspinous dynamic stabilisation (using prototype of current Wallis implant). Maximum follow-up: **17.2 years** Conflict of interest/source of funding: funded by industry	Number of patients analysed: **142** were contacted by phone **Subsequent lumbar surgery:** 21.1% (30/142) (18 of these patients had originally presented with canal stenosis with or without herniated disc; the others had herniated disc only). Of these 30, 26 had the implant removed (18.3% [26/142] of total patients). The following shows the reason for surgery and type of surgery in these patients who underwent subsequent surgery was given: **Reason for surgery** / **Type of subsequent surgery** / **Implant removed** 	Reason for surgery	Fusion	Disc-ectomy	Lamin-ectomy	Foraminal decompression	Un determined	Implant removed
---	---	---	---	---	---	---
*Presumed lack of efficacy**						
Persistent low back pain	8			1	1	8
Canal stenosis	-		1			1
Spondylolisthesis with left leg pain	1					1
*Presumed safety reason**						
Spinous process fracture	2					2
*Unclear whether need for subsequent surgery because of adverse event or lack of efficacy**						
Herniated disc	8	3				8
Fall	1					1
Other undetermined reason	4					5
Total	24	3	1	1	1	26 | *These categories (in italics) reflect interpretation of reported outcomes by the IP team. **Actuarial implant survivorship at 14 years** Lack of implant removal: 81.3±6.8% Lack of need for subsequent lumbar operation endpoint: 75.9±8.3%		**Follow-up issues**: • 241 patients received the procedure. 58.9% (142/294) contacted by phone at 14-year follow-up. **Study design issues**: • Retrospective study **Study population issues:** • 36% treated at more than one lumbar segment. • Not all patients were reported to have LSS. Indications included isolated canal stenosis (43.6%), canal stenosis and herniated disc (21%), herniated disc (31.6%)

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Senegas J (2009)[13]

Case series
France
Recruitment period: 1987–1995
Study population: patients with symptomatic degenerative instability initially scheduled for fusion

n = 241
Mean age: 44.2 years
Sex: 72.9% (78/107) male

Patient selection criteria: devices inserted after decompressive procedures for isolated canal stenosis, recurrent disc herniation, massive primary disc herniation, or canal stenosis decompensated by primary or recurrent herniated discs.

Technique: single or multilevel interspinous dynamic stabilisation (using prototype of current Wallis implant).

Maximum follow-up: 19.6 years

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 107 completed questionnaires

The following outcomes were assessed at mean 13.5 years.

Implant removed and fusion performed: 18.7% (20/107)
An additional 3 patients underwent subsequent surgery but kept the initial implant

Patient Satisfaction
<table>
<tr><th></th><th>Patients who still had implant at follow-up (n = 87)</th><th>Patients where implant removed and fusion performed (n = 20)</th><th>p value</th></tr>
<tr><td>Very satisfied</td><td>58.6% (51/87)</td><td>25% (5/20)</td><td><0.001</td></tr>
<tr><td>Satisfied</td><td>36.8% (32/87)</td><td>40% (8/20)</td><td>-</td></tr>
<tr><td>Dissatisfied</td><td>3.4% (3/87)</td><td>15% (3/20)</td><td>-</td></tr>
<tr><td>Very dissatisfied</td><td>1.1% (1/87)</td><td>20% (4/20)</td><td>-</td></tr>
</table>
Willingness to have the operation again
<table>
<tr><th></th><th>Patients who still had implant at follow-up (n = 87)</th><th>Patients where implant removed and fusion performed (n = 20)</th><th>p value</th></tr>
<tr><td>Certainly</td><td>77% (67/87)</td><td>45% (9/20)</td><td><0.02</td></tr>
<tr><td>Probably</td><td>13.8% (12/87)</td><td>25% (5/20)</td><td>-</td></tr>
<tr><td>Probably not</td><td>8% (7/87)</td><td>10% (2/20)</td><td>-</td></tr>
<tr><td>Certainly not</td><td>1.1% (1/87)</td><td>25% (4/20)</td><td>-</td></tr>
</table>
Long term disability and pain
<table>
<tr><th></th><th>Patients who still had implant at follow-up</th><th>Patients where implant removed and fusion performed</th><th>p value</th></tr>
<tr><td>Mean ODI score</td><td>19.3±16.8 (n = 85)</td><td>30.7±23.3 (n = 20)</td><td><0.04</td></tr>
</table></td>
<td>Not reported</td>
<td>Same patients as Senegas 2007

Follow-up issues:
• Of the 142 (plus 2 new patients) who were contacted by phone in the Senegas 2007 publication, 107 completed questionnaire at long-term follow-up (this is 44.4% [107/241] of all patients treated).

Study design issues:
• Retrospective study
• Leg/back pain scored using VAS. Higher scores indicate more pain
• Short Form-36: each domain scored from 0–100.

Study population issues:
• Diagnosis at baseline: isolated canal stenosis = 22 patients, canal stenosis and herniated disc = 13</td>
</tr>
</table>

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments

Mean low back pain score (VAS)	25.6±22.1 (n = 86)	43.7±29.9 (n = 19)	<0.003
Mean leg pain score (VAS)	19.4±23.1 (n = 86)	44.7±32.9 (n = 85)	<0.001

Short Form-36 (quality of life measure) mean scores

	Patients who still had implant at follow-up	**Patients where implant removed and fusion performed (n = 20)**	**p value**
Physical function	–13.0 (n = 85)	-29.8	0.05
Reduction in health-related physical limitation	–17.6 (n = 86)	-37.2	0.06
Reduction in bodily pain	–12.6 (n = 87)	-23.1	0.07
General health	–4.6 (n = 86)	-12.6	-
Vitality (energy levels)	–3.8 (n = 85)	-8.4	-
Social functioning	–6.3 (n = 87)	-22.7	<0.02
Reduction in emotional problems	–8.9 (n = 84)	-21.2	-
Mental health	–3.6 (n = 85)	-6.3	-

Table above indicates that patients who still had the implant had better quality of life than those where the implant was removed and fusion performed in terms of physical and social functioning.

patients, isolated recurrent disc = 21 patients ad other = 4 patients

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Sell P (2010)[7]

Unpublished abstract of a case series
UK
Recruitment period: not reported
Study population: patients with clinical and radiological evidence of spinal stenosis
n = 69
Mean age: 67 years
Sex: not reported

Patient selection criteria: according to recommendations of clinical trials groups for the X-STOP (such as sitting tolerance of greater than 30 minutes)

Technique: X-STOP (St. Francis Medical Technologies, Inc, CA) (no other details provided)
Maximum follow-up: 24 months
Conflict of interest/source of funding: no commercial or grant support</td>
<td>Number of patients analysed: 66

Pain resolution (VAS) and disability (ODI)
Clinical outcome data at average of 10 months was available for 66 patients.
<table>
<tr><th></th><th>Mean preoperative score</th><th>Mean postoperative scores</th></tr>
<tr><td>ODI</td><td>42%</td><td>27%</td></tr>
<tr><td>VAS leg pain</td><td>7.2</td><td>4.4</td></tr>
<tr><td>VAS back pain</td><td>4.8</td><td>3.6</td></tr>
</table>
– The authors considered a 16-point change in ODI score to represent a clinically significant improvement. At least half of the patients in the study did not achieve this and 25% (17/69) had a dramatic improvement of greater than 24 points.
– VAS scale was not described but appears to be on a 0 to 10 scale with 10 indicating higher pain.

Revisions
There has been a 27% (18/66) failure rate so far. Failure was considered when removal and revision was required (no other details provided).</td>
<td>Not reported</td>
<td>Follow-up issues:
• Not described. Data on 3 patients at 10 months was not available. This may have been because these patients had not yet been followed up for 10 months but it was not reported in the abstract.

Study design issues:
• This information has not yet been accepted for publication but has been included because of the high revision rate. (It is available as an abstract on the BASS website).</td>
</tr>
</table>

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
Barbagello GMV (2009)[8] **Case series** Italy Recruitment period: 2005 – 2007 Study population: neurogenic intermittent claudication caused by degenerative LSS or spondylolisthesis (grade 1 or lower), low-back pain from facet joint syndrome and a combination of more than one of these n = **69 (92 implantations)** Mean age: 69.3 years Sex: 49% female Patient selection criteria: all patients had pain on flexion Technique: fluoroscopy to identify correct space (and later to confirm position), implantation of X-STOP (St. Francis Medical Technologies, Inc, CA) with the patient prone (n=65) or lateral decubius under general anaesthesia (n=4) Mean follow-up: **23 months** Conflict of interest/source of funding: none	Number of patients analysed: **66** ***Complications*** There was 10.1% (7) postoperative and 1.7% (1) intraoperative complications (none were neurological)		**Study design issues**: • The purpose of this study was to analyse a series of complications at a single institution. • The analysis showed that the patients' anatomy appeared to play a large role in the occurrence of complications. The authors developed an anatomical scoring system to better assess each patient's anatomical features preoperatively to prevent the use of the device in unsuitable patients.

Patient	Indication	Level	Complication	Timing of complication	Revision surgery	Trauma
1	LSS, Neurogenic claudication	L3/L4, L4/L5	L5 spinous process fracture	Intraoperative	No	No
2	Spondylolisthesis, neurogenic claudication	L4/L5	Dislocation	2 weeks	Yes	No
3	LSS, neurogenic claudication	L3/L4, L4/L5	Dislocation of both implants	4 days for both	Yes	No
4	Spondylolisthesis, neurogenic claudication	L4/L5	Dislocation	6 days	Yes	No
5	LSS, neurogenic claudication	L3/L4, L4/L5	Device malpositioning (1 implant)	6 weeks	Yes	No
6	LSS, facet joint syndrome	L4/L5	L5 spinous process fracture	1 week	Yes	Yes
7	LSS, facet joint syndrome	L3/L4, L4/L5	L4 spinous process fracture	6 months	Yes	No
8	LSS, Neurogenic claudication	L3/L4, L4/L5	L4 spinous process fracture	4 months	Yes	No

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
Bowers C (2010)[15] **Case series** USA Recruitment period: 2005 – 2007 Study population: MRI-confirmed symptomatic moderate to severe LSS and foraminal stenosis including neurogenic claudication, lower back pain and leg pain n = **13** Mean age: 74.6 years Sex: 38.5% female Patient selection criteria: patients with history of neurogenic claudication with clear symptom amelioration by bending forward Technique: implantation of X-STOP (St. Francis Medical Technologies) Mean follow-up: **23.4 months** Conflict of interest/source of funding: none	Number of patients analysed: **13** ***Resolution of pain*** 100% of patients reported initial pain improvement (average 72% improvement). However pain returned in 77% (10/13) of patients. ***Revision surgery*** 46% (6/13) had laminectomy and/or fusion because of recurrent pain at between 4 and 27 months after the initial procedure.	***Complications*** Spinous fracture in 23% (3/13) with a recurrence of symptoms (treated with decompressive laminectomy with spinal fusion). New-onset radiculopathy at L3 in 15% (2/13). In 1 this was at the same level as the X-STOP device and in another it was at an adjacent level (caused by a herniated disk). Both required surgery but 1 denied surgery because of the desire to avoid open surgery.	**Study design issues**: • Retrospective study **Study population issues:** • Nine at L4-5 and 4 at both L3-4 and L4-5. • Stenosis was severe in 69% (9/13) and moderate in 31% (4/13). • 38% (5/13) had degenerative spondylolisthesis and 1 had mild scoliosis.

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.

Study details	Key efficacy findings	Key safety findings	Comments
Verhoof OJ (2008)[9] **Case series** The Netherlands Recruitment period: 2003 – 2005 Study population: symptomatic degenerative LSS caused by degenerative spondylolisthesis with low back pain, neurogenic claudication and radiculopathy n = **12** Mean age: 67.5 years Sex: 75% female Percentage of degenerative spondylolisthesis: less than 30% in all patients with an average 19.6% degenerative slip (9 had less than 25% which is less than grade 1 degenerative spondylolisthesis) Patient selection criteria: patients refractory to conservative care for more than 6 months Technique: X-STOP (St. Francis Medical	Number of patients analysed: **12** 10 had operations at L4/L5 and 2 had both L3/L4 and L4/L5. ***Pain resolution / recurrence*** 8 of 12 patients had significant improvement of pain, neurogenic claudication and radiculopathy but 4 had no symptom relief. After 12 weeks, 2 patients with an initial relief of symptoms suffered a recurrence of pain, neurogenic claudication and radiculopathy. At 24 month follow-up, an additional patient had recurrence. All 7 patients with no symptom relief or recurrence of symptoms had a postoperative MRI which showed that spinal stenosis had not changed significantly since the procedure. Mean postoperative anteroposterior axial cross sectional diameter was 6.80 mm and mean sagittal cross sectional diameter was 6.91 mm (preoperative values of these patients were not significantly different from the 5 patients with pain relief and no recurrence). Six of these patients had less than grade 1 degenerative spondylolisthesis (less than 25% degenerative slip) and one had 27.6% degenerative slip. ***Revisions*** All 7 patients (58.3%) with no symptom relief or recurrence of symptoms underwent surgical re-intervention which involved removing the X-STOP and performing decompression with posteriolateral fusion.	***Complications*** There were no perioperative complications.	**Follow-up issues**: • Clinical and radiographic examination at 6 and 12 weeks and 12 and 234 months. **Study design issues**: • Retrospective **Study population issues**: • All patients had degenerative spondylolisthesis.

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Technologies, Inc, CA) implantation with the use of general anaesthesia after radiographic identification of the surgical level Mean follow-up: **30.3 months** Conflict of interest/source of funding: none			

Abbreviations used: CSF, cerebrospinal fluid; CT, computed tomography; ITT, intention-to-treat; LSS, lumbar spinal stenosis; MCS, mental component summary measure; MRI, magnetic resonance imaging; NA, not applicable; NSAID, non-steroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; PCS, physical component summary measure; PLIF, posterior lumbar interbody fusion; SD, standard deviation; SF-36, short-form health survey (36 questions); VAS, visual analogue scale; ZCQ, Zurich Claudication Questionnaire.			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Epstein (2008)[10] **Case report of haematoma and cellulitis** USA n = **2** Technique: X-STOP (Kyphon Inc, St. Francis Medical Technologies, Inc, CA) Conflict of interest/source of funding: not reported	***Case 1*** A male in his 70s with significant comorbidities alongside LSS (atrial fibrillation, peripheral vascular disease and mechanical aortic and mitral valves, requiring warfarin) had X-STOP at the L3/4 and L4/5 levels. One day after surgery, large **subcutaneous postoperative haematoma** developed after he was restarted on his intravenous heparin/warfarin. The patient required surgical removal of the haematoma 9 days after the original surgery. ***Case 2*** A woman in her 80s with significant comorbidities (diabetes, hypertension, hypercholesterolaemia, obesity and hypothyroidism) had elective X-STOP procedure at L4/L5 and was discharged within 24 hours. Within 5 days, she was readmitted for **cellulitis** for the wound and severe low back pain. MRI demonstrated superficial wound collection which was treated with plastic surgery and intravenous linezolid (on recommendation by infectious disease consultants). The patient was discharged after the cellulitis cleared 11 days later.		**Issues:** • These reports were both reported in personal communication
Epstein (2009)[11] **Case report of foot drop** USA n = **2** Technique: X-STOP (Kyphon Inc) Conflict of interest/source of funding: none	An 84 year old male (with hypertension) was treated with X-STOP for severe L4/L5 stenosis with neurogenic claudication and lower extremity sciatica associated with grade 1 degenerative spondylolisthesis. Hospital records showed no evidence of foot drop on either side but a loss of lower extremity reflexes and mild diminution of pin appreciation at L5/S1. Immediately after the procedure, the patient developed **complete bilateral foot drop**. The device extruded 3 months later and had to be removed. The patient was not offered treatment to address the foot drop or persisting symptoms. Nine months later, the patient still exhibited bilateral foot drop with moderate proximal weakness, alongside the original symptoms. MRI and CT revealed severe congenital lumbar stenosis and ossification/hypertrophy of the yellow ligament from L1-S1 alongside previously documented degenerative spondylolisthesis at L4/L5. The patient was treated with L1-S1 laminectomy with non-instrumented posteriolateral fusion at the L4/L5 level. The patient had severe osteoporosis. The patient reported his pain on a scale of 1 to 10 (10 being worst pain) to have decreased from 10 to 3. The bilateral foot drop completely resolved on the left and partially on the right. Pin appreciation was improved on both sides.		

Efficacy

Pain resolution

An RCT of 191 patients reported that the symptom severity (measured on the Zurich Claudication Questionnaire [ZCQ]) had improved by 45.4% in the 100 patients treated with the procedure compared with 7.4% in the 91 patients treated with conservative therapy from baseline to 2-year follow-up ($p < 0.001$). The number of patients with a clinically significant improvement at 2 years was 60.2% (56/93) and 18.5% (15/81) respectively ($p < 0.001$; definition of clinical significant improvement not reported; 7 and 10 patients respectively were lost to follow-up for reasons including death unrelated to treatment, failure to complete outcome questionnaire and withdrawal from study)[1].

A non-randomised controlled study of 61 patients reported that the 30 patients treated with the procedure and 31 patients treated with posterior lateral interbody fusion both had significant decreases in visual analogue scores (VAS, appears to be on scale of 0 to 10 with 10 being worst pain) for low back pain and leg pain from baseline to a mean 40.4 months and 38.4 months follow-up, respectively (4.7 to 2.4 vs. 5.5 to 3.3 for low back pain and 6.9 to 2.4 vs. 6.5 to 2.6 for leg pain; $p < 0.001$ from baseline to follow-up for all scores but no significant difference between groups)[4].

A non-randomised controlled study which compared 18 patients treated with the procedure with 24 patients treated with PLIF reported that both groups improved significantly in VAS (on scale 0 – 9 or 0 – 10 with higher numbers being worst pain) for lower leg pain and lower back pain from baseline to 1-year follow-up but there were no significant differences between the groups (approximately 7.4 to 3.2 vs. 7.9 to 3.0 for low back pain and 8.1 to 2.9 vs. 7.6 to 2.4 for lower leg pain). The same study reported a significantly improved ODI score in both groups in the same time period but again there was no significant difference between the groups (approximately 55 to 28 vs. 60 to 25, respectively; $p < 0.05$)[5].

A case series of 175 patients reported a significant decrease in VAS for leg pain postoperatively (scale 0 – 100 with 100 being worst pain; 61.1 to 38.9; $p < 0.005$). These changes remained stable throughout the 2-year follow-up[6].

A case series of 241 patients in which 107 patients completed questionnaires at final follow-up reported significantly lower mean low back pain score and mean leg pain score (measured on VAS, higher scores indicate greater pain) in patients who still had the implant at mean follow-up of 13.5 years ($n = 86$) compared with patients in whom the implant had been removed and fusion performed ($n = 20$) in the same follow-up period (low back pain: 25.6 vs. 43.7, $p < 0.003$; leg pain: 19.4 vs. 44.7, $p<0.001$)[13].

A case series of 13 patients reported that all patients had an initial improvement of their symptoms, but that pain returned in 77% (10/13)[15].

Physical function / mobility

The RCT of 191 patients reported that physical function on the ZCQ had improved by 44.3% in the 100 treated with the procedure compared with a decrease of 0.4% in the 91 treated with conservative therapy from baseline to 2-year follow-up ($p < 0.001$). The number of patients with a clinically significant improvement at 2 years was 57% (53/93) and 14.8% (12/81) respectively ($p < 0.001$; definition of clinical significant improvement not reported)[1].

The non-randomised study of 61 patients reported a significant decrease in Oswestry Disability Index (ODI; scale 0 – 100 with 100 being greatest disability) from baseline to last follow-up for both patients treated with the procedure and those treated with interbody fusion (23.0 to 11.3% vs. 20.5 to 10.9%) $p < 0.001$; no significant difference between groups; mean 40.4 months and 38.4 months follow-up, respectively)[4].

A non-randomised comparative study of 60 patients, which compared 30 patients treated with decompression and an interspinous implant with 30 patients with decompression alone showed significant improvement in ODI scores in both groups at 12 months (from 48 to 18 and 38 to 19 respectively) but this difference was not significant between groups[14].

The case series of 175 patients reported a decrease in ODI from 32.6 to 22.7% postoperatively with a score of 20.3% at 24-month follow-up (significance level not reported)[6].

The case series of 241 patients with 107 patients who responded to questionnaires reported a significantly lower mean ODI score in patients who still had the implant at mean follow-up of 13.5 years ($n = 85$) compared to patients where the implant had been removed and fusion performed ($n = 20$) in the same follow-up period (19.3 vs. 30.7, $p < 0.04$)[13].

The unpublished abstract reported that mean ODI score decreased from 42 to 27% postoperatively. At least half of the patients were considered to have a clinically significant improvement (reduction of 16 points) and 25% (17/69) had a dramatic improvement (reduction of > 24 points)[7].

Quality of life

The RCT of 191 patients showed a significantly better SF-36 score in physical function, health-related physical limitations, bodily pain, energy levels, social functioning and mental health in patients treated with the procedure over those who had conventional treatment at 2-year follow-up (first 3 domains $p \leq 0.001$ [59.3 vs. 41.4, 51.4 vs. 28.2, and 53.8 vs. 34.5], next 3 domains $p < 0.03$ [58.3 vs. 49.7, 81.2 vs. 70.4, 79.7 vs. 73.2])[2].

Another publication from the same RCT which included a subset of 75 patients who had degenerative spondylolisthesis reported a significantly better patient

component summary score on the SF-36 in the 42 patients treated with the procedure than the 33 patients treated with conservative treatment at 2-year follow-up (p-values not reported)[3].

The case series of 241 patients with 107 patients who responded to questionnaires reported a significantly better SF-36 physical function and social function scores in patients who still had the implant at mean follow-up of 13.5 years (n = 85 and 87 respectively) compared to patients where the implant had been removed and fusion performed (n = 20) in the same follow-up period (–13 vs. –29.8, p = 0.05 and –6.3 vs. –22.7, p < 0.02 respectively)[13].

Patient satisfaction

A publication from the RCT of 191 patients with a subset of 75 patients with degenerative spondylolisthesis reported that the 42 patients treated with the procedure were significantly more satisfied after their treatment than the 33 patients treated with conservative therapy (1.55 vs. 2.80 on ZCQ patient satisfaction domain; scale 0 to 5 with 0 completely satisfied; p value not reported)[3].

The case series of 241 patients which reported on 107 patients who had completed questionnaires at the final follow-up reported that 59% (51/87) patients who still had the implant at mean follow-up of 13.5 years were very satisfied compared with 25% (2/20) patients where the implant had been removed and fusion performed in the same follow-up period (p<0.001)[13].

Revision surgery

The RCT of 191 patients reported that a number of patients in both groups converted to laminectomy because of unresolved stenosis. This included 6% (6/100) in the intervention group and 26% (24/91) in the control group (time of conversion not reported)[1].

The non-randomised comparative study of 60 patients reported that 7% (2/30) of those treated with the implant required revision with pedicle screw fusion (time and reason for the revision not reported)[14].

The case series of 175 patients reported that 4.6% (8/175) of patients required removal of the device because the procedure was unsatisfactory. These patients were then treated by microsurgical decompression (timing not reported)[5].

A case series of 241 patients with 142 patients who were contacted by telephone reported 18% (26/142) patients had the stabilisation implant removed at follow-up of 9 to 17.2 years. This equates to an actuarial survivorship of 81% at 14-year follow-up. The same study reported that 21% (30/142) underwent subsequent surgery within the same follow-up period; 24 of these procedures were fusion[12].

An unpublished abstract of 69 patients treated with the procedure reported that 27% (18/66) of patients required removal of the spacer and revision surgery[6].

The case series of 13 patients reported that 46% (6/13) of patients required laminectomy and/or fusion because of recurrent pain at between 4 and 27 months after the procedure[15].

A case series of 12 patients reported that 4 patients with no symptom relief after the procedure and 3 patients with symptom recurrence (58.3%, 7/12) required surgical re-intervention which involved removing the device and performing decompression with posteriolateral fusion[9].

Safety

Death

The RCT of 191 patients reported that one with a history of cardiovascular disease developed pulmonary oedema 2 days after the device implantation and subsequently died[1].

Haematoma

One case report described a man who developed a large subcutaneous haematoma 1 day after surgery after he was restarted on heparin and warfarin. This patient was in his 70s and had significant comorbidities including atrial fibrillation, peripheral vascular disease and mechanical aortic and mitral valves, requiring warfarin. The patient required surgical removal of the haematoma 9 days after the original surgery[10].

Related to the device

The RCT of 191 patients reported 1 malpositioned implant and 1 implant migration after the patient fell (time of occurrence not reported). The migrated implant was removed without sequelae (treatment for malpositioned implant not reported)[1].

The RCT of 75 patients reported that 1 of the 42 patients treated with the device had a malpositioned implant which was later detected on radiographic examination[3].

The non-randomised study of 61 patients reported a fractured device in one of the 30 patients treated with the device (time of occurrence and further details not reported)[4].

A case series of 69 patients reported dislocation of the device in 4 devices (3 patients) at 4-days, 6-day and 2-week follow-up. The same study reported device malpositioning in 1 patient. All 4 patients had revision surgery[8].

Spinous fracture

The RCT of 191 patients reported a spinous process fracture detected on 6-month radiography in 1 of the 100 patients treated with the device. No more treatment was required[1].

The non-randomised study of 60 patients reported dislocation of the implant due to fracture of the spinous process in 1 patient (sequelae not described)[14].

A case series of 69 patients reported spinous process fracture in 1 patient intraoperatively and 3 patients postoperatively (at 1 week, 4 and 6 months). All but the one which occurred intraoperatively were treated with revision surgery. One was caused by trauma[8].

Other

The RCT of 191 patients reported the following intraoperative events in 1 patient in each of the 100 patients treated with the device: respiratory distress, ischaemic episode without sequelae, wound dehiscence, wound swelling, haematoma, and incision pain. One patient had increased pain at the level of the implant 382 days after the procedure[1].

The RCT of 75 patients reported an incisional complication which resolved after 1 week with oral antibiotic therapy[3].

An unpublished abstract of a case series of 69 patients reported that VAS for leg pain and back pain both decreased postoperatively (appears to be on scale of 0 – 10 with 10 being greatest pain; 7.2 to 4.4 and 4.8 to 3.6, respectively; p value not reported)[7].

The non-randomised trial of 61 patients reported that 1 of the 30 treated with the device required an additional operation because bony materials between the nerve root and the implant were compressing the operation site (time of occurrence and further details not reported)[4].

The non-randomised comparative study of 60 patients reported a cerebrospinal fluid leak in 1 patient in each treatment group (subsequent treatment and sequelae not described)[14].

A case report described a woman developing cellulitis 5 days after implantation. The woman was in her 80s and had significant comorbidities including diabetes, hypertension, hypercholesterolaemia, obesity and hypothyroidism. This was treated with plastic surgery and intravenous linezolid and the patient was discharged after the cellulitis cleared 11 days later[10].

A case report described an 84-year old male who developed complete bilateral foot drop immediately after the procedure. The device extruded 3 months later and had to be removed. The patient was not offered treatment to address the foot

drop or persisting symptoms. Nine months later at another centre, the patient still exhibited bilateral foot drop with moderate proximal weakness, alongside the original symptoms. The patient was treated with L1-S1 laminectomy with non-instrumented posteriolateral fusion at the L4/L5 level. After treatment, the patient reported his pain on a scale of 1 to 10 (10 being worst pain) to have decreased from 10 to 3; the bilateral foot drop completely resolved on the left and partially on the right[11].

Validity and generalisability of the studies

- The original overview included 1 RCT[1] (n = 191, included in this overview) which compared this procedure with conservative treatment and 1 case series (n = 10). The maximum follow-up was 2 years. This overview includes an additional 937 patients in non-randomised studies, case series and case reports with a maximum follow-up of 19.6 years. There are also a few additional reports of safety events such as haematoma and foot drop which were not reported previously.

Existing assessments of this procedure

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S). Horizon Scanning Technology Prioritising Summaries: X STOP® Interspinous Process Decompression System for spinal stenosis (March 2006)
Recommendation: Further long-term studies comparing the device to other surgical options are required before the safety and efficacy of this device can be confirmed. Therefore, due to the limited evidence available, it is recommended that the following be conducted: monitor.
Note: Medical Services Advisory Committee (MSAC) has commissioned full HTA

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

- Laser lumbar discectomy. NICE interventional procedures guidance 27 (2003). Available from http://www.nice.org.uk/guidance/IPG27
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedures guidance 83 (2004). Available from http://www.nice.org.uk/guidance/IPG83

- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedures guidance 141 (2005). Available from http://www.nice.org.uk/guidance/IPG141
- Percutaneous disc decompression using coblation for lower back pain. NICE interventional procedures guidance 173 (2006). Available from http://www.nice.org.uk/guidance/IPG173
- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedures guidance 306 (2009). Available from http://www.nice.org.uk/guidance/IPG306
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedures guidance 300 (2009). Available from http://www.nice.org.uk/guidance/IPG300
- Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedures guidance 319 (2009). Available from http://www.nice.org.uk/guidance/IPG319

Clinical guidelines

- Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009). Available from http://www.nice.org.uk/guidance/CG88 (patients with stenosis were excluded from the guideline)

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.

Tim Piggott, Jake Timothy, Society of British Neurological Surgeons.

- Advisers noted that this has been widely used but surgeons are losing their initial enthusiasm. One Adviser noted that the indications which he uses this procedure for has changed and he performs it less often than previously (he believes this is still effective in younger patients with foraminal stenosis rather than central stenosis).
- Comparators include laminectomy, foraminectomy, and standard open decompressive surgery with an inter-laminar approach.
- One Adviser notes that this procedure does not have the same risks associated with laminectomy (such as cerebrospinal fluid leak, nerve damage and risk of infection).

- Key efficacy outcomes include pain relief (such as claudicant leg pain) and Oswestry Disability Index, Zurich Claudication questionnaire.
- Anecdotal events include infection and movement after placement.
- Theoretical events include misplacement.
- There were concerns that the early results are not maintained. This problem also exists with open surgery, though open surgery appears to be efficacious for longer.
- Training on a course with cadavers is required.
- The procedure should be performed with access to fluoroscopy.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme sent questionnaires to 2 trusts for distribution to patients who had the procedure (or their carers), but did not receive any completed questionnaires.

Issues for consideration by IPAC

- A number of devices which have been used for this procedure include X-STOP, Wallis, Diam and Coflex (X-STOP has been owned by a number of manufacturers over the last few years but is now owned by Medtronic).
- One of the Specialist Advisers noted a randomised trial of X-STOP compared to laminectomy at Queen's Square in London.
- There is an RCT in the US recruiting patients with spinal stenosis to compare Coflex with fusion following decompressive laminectomy. The study aims to recruit 460 patients who must have undergone at least 1 epidural steroid injection and at least 6 months of conservative treatment (funded by Paradigm Spine; NCT00534235).
- A phase III RCT in the US comparing dynamic stabilisation (using Wallis mechanical normalisation system) with conservative treatment (exercise and injections) for patients with low back pain is reported to have enrolled 300

patients and primary data collection ended in 2006. The study is reported to be ongoing (funded by Zimmer Spine; NCT00134537).

- The manufacturers have stated that there is an ongoing German RCT comparing Coflex and decompression with decompression only (the study aims to recruit 230 patients and report 2-year follow-up).

Equality and diversity

- Lumbar spinal stenosis is related to older age and the evidence reflects this.
- Additional risk factors include congenital narrowing of the spinal canal (much less common than degenerative), osteoarthritis (degenerative), hyperparathyroidism, Paget's disease, ankylosing spondylitis, Cushing's syndrome, and acromegaly. The evidence did not explicitly state if these conditions existed in the patients included in the studies.

References

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

2. Hsu KY, Zucherman JF, Harjen CA et al. (2006) Quality of life of lumbar stenosis-treated patients in whom the X STOP interspinous device was implanted. Journal of neurosurgical spine 5:500–7.

3. Anderson PA, Tribus CB, and Kitchel SH. (2006) Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar denerative spondylolisthesis. Journal of neurosurgical spine 4:464–71.

4. Park S-C, Yoon S-H, Hong Y-P et al. (2009) Minimum 2-year follow-up result of degenerative spinal stenosis treated with Interspinous U (Coflex^{TM}). The Korean Neurosurgical Society 46:292–9.

5. Kong D-S, Kim E-S, Eoh W. (2007) One-year outcome evaluation after interspnious implantation for degenerative spinal stenosis with segmental instability. Journal of Korean Medical Science 22:330–5.

6. Kuchta J, Sobottke R, Eysel P et al. (2009) Two-year results of interspinous spacer (X-Stop) implantation in 175 patients with neurologic intermittent claudication due to lumbar spinal stenosis. European Spine Journal 18:823–9.

7. Sell P and Newey M. (2010) The early clinical outcome of a consecutive series of interspinous distraction devices [Unpublished abstract]

8. Barbagello GMV, Olindo G, Corbino L et al. (2009) Analysis of complications in patients treated with the X-STOP interspinous distraction process decompression system: proposal for a novel anatomic scoring system for patient selection and review of the literature. Neurosurgery 65:111–9.

9. Verhoof OJ, Bron JL, Wapstra FH et al. (2008) High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. European Spine Journal 17:188–92.

10. Epstein NE. (2008) How often is minimally invasive minimally effective: what are the complication rate for minimally invasive surgery? Surgical Neurology 70:386–9.

11. Epstein NE. (2009) X-Stop: Foot drop. The Spine Journal 9:e6–9.

12. Senegas J, Vital JM, Pointillart V et al. (2007) Long-term actuarial survivorship analysis of an interspinous stabilization system. European Spine Journal 16:1279–87.

13. Senegas J, Vital JM, Pointillart V et al. (2009) Clinical evaluation of a lumbar interspinous dynamic stabilization device (the Wallis system) with a 13-year mean follow-up. Neurosurgical Review 32:335–41.

14. Richter A, Schutz C, Hauck M et al. (2010) Does an interspinous device (Coflex) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. European Spine Journal 19 (2) 283–289.

15. Bowers C, Amini A, Dailey AT et al. (2010) Dynamic interspinous process stabilization: review of complications associated with the X-Stop device. Neurosurgical Focus 28 (6) E8–2010.

Appendix A: Additional papers on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication

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
Arrotegui I (2010) Coflex device for lumbar disc surgery: Avoid the last step: Lumbar instability. Spanish Journal of Surgical Research 13: 7–11.	Randomised controlled study n = 494 (247 with lumbar disc surgery and Coflex device vs 247 with lumbar disc surgery alone) Follow-up = 193 completed 3 years and 102 had 7 years	Long-term success rate with Coflex: 84.6% vs 70% without ($p < 0.01$). Complications: 2 spinous process device infections. (Randomisation after lumbar disc surgery. Efficacy outcomes only reported in abstract and not well described, technique not described, statistical methods not reported.)	Poor-quality study.
Barbagallo GMV, Corbino LA, Olindo G et al. (2010). The "sandwich phenomenon": A rare complication in adjacent, double-level X-stop surgery: Report of three cases and review of the literature. Spine 35 (3) E96-E100.	Case reports of safety n = 3 with X-Stop	Spontaneous fracture of L4 in 3 patients (who presented with recurrent symptoms at 4, 6 and 18 months). Two had removal, decompression and fixation, but the 1 who presented later did not consent to revision surgery.	This is a duplicate reporting of this outcome in these patients, which was reported in Barbagello 2009 in table 2.
Bhadra AK, Raman AS, Tucker S et al. (2008) Interspinous implant in lumbar spinal stenosis: A prospective cohort European Journal of Orthopaedic Surgery and Traumatology 18:489–3.	Case series n = 45 treated with X-STOP Follow-up = 30 with minimum of 24 hours, 15 with minimum 18 months	Average VAS of back and leg pain improved from 6.7 and 6.8 to 2.7 and 2.8 68% had improved walking distance Average ODI improved from 42% to 16.38% ($p < 0.0001$)	Larger studies in table 2.
Brussee P, Hauth J, Donk RD et al. (2008) Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication. European Spine Journal 17:200–3.	Case series n = 65 treated with X-Stop Mean follow-up = 1 year	31.1% had a good outcome (mean score on Zurich Questionnaire for satisfaction at 2.0, mean improvement of severity score of at least 0.5 and also for vitality score)	Larger studies in table 2.

Chou R, Baisden J, Carragee E et al. (2009) Surgery for low back pain: A review of the evidence for an American Pain Society clinical practice guideline. Spine 34:1094–109.	Systematic review	Summary of results of Zucherman and Anderson included in table 2 of this overview.	No new information (studies already included in table 2).
Chung KJ, Hwang YS, Koh SH (2009) Stress fracture of bilateral posterior facet after insertion of interspinous implant. Spine 34:E380–3.	Case report n = 1 Follow-up = 6 years	A 64-year old woman treated with Coflex for low back pain, radicular pain in her left leg and spinal stenosis associated with degenerative spondylolisthesis presented with fracture of bilateral inferior articular processes 6 years later.	This event has been reported in table 2.
Errico TJ, Kamerlink JR, Quirno M et al. (2009) Survivorship of coflex Interlaminar-Interspinous Implant. SAS Journal 3 (2) 59-67.	Case series n = 127 with Coflex Follow-up = 6.3 years	Mean severity of low back pain decreased by 33% at 2 and 5 years ($p < 0.001$ at both times) and leg pain decreased by 66% at the same times ($p < 0.001$ for both). 1% had broken wing of implant, 5% had a displaced 'U' portion of implant, 2% had removed implant.	Larger studies in table 2.
Kondrashov DG, Hannibal M, Hsu KY et al. (2006) Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: A 4-year follow-up study. Journal of Spinal Disorders and Techniques 19: 323–27.	Case series n = 18 treated with X-STOP Mean follow-up = 51 months (4.2 years)	Mean improvement in ODI was 29. 78% (14/18) had successful outcomes (at least 15 point improvement).	Larger studies in table 2.
Korovessis P, Repaintis T, Zacharatos S et al. (2009) Does Wallis implant reduce adjacent segment degeneration above lumbosacral instrumented fusion? European Spine Journal 18:803–40.	Non randomised controlled trial n = 50 (25 treated with Wallis vs. 25 without interspinous implant) Mean follow-up = 60 months	SF-36 and ODI improved postoperatively but this was more favorable in the intervention group at the final evaluation ($p < 0.05$). Intraoperative dural violation occurred (immediately sutured with no further problems) in 1 patient with the implant and 2 in the control group. One patient in each	All 50 patients initially enrolled in the study had decompression and posterior transpedicular rigid fixationand fusion. It is not clear if this was at the time of the procedure or at an earlier time so it was difficult to determine the efficacy of interspinous distraction.

		group had unsymptomatic remote osteoporotic compression fractures.	
Lee J, Hida K, Seki T et al. (2004) An interspinous spinous distractor (X STOP) for lumbar spinal stenosis in elderly patients: Preliminary experiences in 10 consecutive cases. Journal of Spinal Disorder Technology 17:72–7.	Case series n = 10 treated with X-STOP Mean follow-up = 11 months	Cross sectional area of dural sac increased 22.3% and intervertebral foramina increased by 36.5%. 70% of patients were satisfied with the results.	Larger studies in table 2.
Miller JD, Miller MC, and Lucas MG. (2010) Erosion of the spinous process: a potential cause of interspinous process spacer failure. Journal of Neurosurgery Spine 12 (2) 210-213.	Case report n = 2 Follow-up = 11 and 15 months	2 cases of erosion of the spinous processes adjacent to the interspinous process spacers discovered 15 and 11 months after the procedure.	Outcome reported in table 2.
Nachanakian A, Alaywan M, Achkar K et al. (2010) Posterior dynamic stabilisation. Pan Arab Journal of Neurosurgery 14 (1) 33-139.	Case series n = 9 with Coflex Follow-up = 9 months	Most patients had good relief from symptoms. Satisfaction in 75% of patients. No surgical complications.	Larger studies in table 2.
Nardi P, Cabezas D, Rea G et al. (2010) Aperius PercLID stand alone interspinous system for the treatment of degenerative lumbar stenosis: Experience on 152 cases. Journal of Spinal Disorders and Techniques 23 (3) 203-207.	Case series n = 152 with Asperius PercLID system Follow-up = not reported	Significant improvement in VAS for low-back and leg pain and in ZCQ scores for symptom severity, physical function, patient satisfaction and quality of life (EuroWol-5D) 2 cases of therapeutic failure requiring a removal and foraminotomy.	Larger studies in table 2.
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 (4) 285-291.	Case series n = 27 Follow-up = 12.6 months	VAS of leg and back pain decreased significantly 5 complications related to fixation	Larger studies in table 2.
Sell P. (2010) The clinical, biomechanical and radiological features of failure of an interspinous distraction device. (unpublished abstract)	Case series n = 45 treated with X-Stop Follow-up = 1 year	24% (11/45) failure rate (with revision surgery) exhibiting in 2 modes: some failed to improve after the procedure and some had deterioration after an initial improvement. Feature of failures was bone	Patients are included in unpublished abstract already included in table 2.

		resorption around the implant. One spinous process fracture.	
Siddiqui M, Nicol M, Karadimas E, et al. (2005) The positional magnetic resonance imaging changes in the lumbar spine following insertion of a novel interspinous process distraction device. Spine 30:2677–2682	Case series n = 12 (17 levels) treated with X-STOP Follow-up = not reported	Dural sac area increased from 77.8 mm to 93.4 mm after surgery in the standing position (p = 0.006).	Larger studies in table 2.
Siddiqui M, Karadimas E, Nicol M et al. (2006) Influence of X Stop on neural foramina and spinal canal area in spinal stenosis. Spine 31:2958–2962	Case series n = 26 treated with X-STOP Follow-up = not reported	Significant increase in dimensions of neural foramen and canal area after surgery	Larger studies in table 2.
Siddiqui M, Smith FW, Wardlaw D. (2007) One-year results of X Stop interspinous implant for the treatment of lumbar spinal stenosis. Spine 32:1345–1348	Case series n = 40 treated with X-STOP Follow-up = 1 year	Only 24 completed questionnaires. Of these, 54% had clinically significant improvement in symptoms, 33% in physical function and 71% were satisfied with the procedure. 29% required caudal epidural 12 months later because of recurrence of claudication	Larger studies in table 2.
Sobottke R, Schlüter-Brust K, Kaulhausen T et al. (2009) Interspinous implants (X Stop®, Wallis®, Diam®) for the treatment of LSS: Is there a correlation between radiological parameters and clinical outcome? European Spine Journal 18:1494–1503.	Non-randomised controlled trial n = 129 (78 X-STOP, 33 Diam, 18 Wallis) Mean follow-up = 202 days (35.7% of patients) and 527.2 days (8.5% of patients)	X-STOP improved the radiological parameters more than Diam and Wallis but there was no significant difference in symptom relief.	Studies with more patients at longer periods of follow-up in table 2.
Yano S, Hida K, Seki T et al. (2007) A new ceramic interspinous process spacer for lumbar spinal canal stenosis. Spine 63:ONS108–13.	Case series n = 19 treated with a ceramic spacer Follow-up = approximately 3 years	Outcomes on VAS and ZCQ were satisfactory (VAS 6.88 to 3.00, BCQ symptom severity from 2.94 to 1.92 and physical function from 2.51 to 1.73).	Larger studies included in table 2.
Zucherman JF, Hsu KY, Hartjen CA et al. (2004) A prospective randomized multi-centre study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant:1-year results	RCT n = 191 treated with X-STOP Follow-up = 1 year	Outcomes reported above in Zucherman JF (2005)[1].	A later publication from this study is in table 2.

Appendix B: Related NICE guidance for interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication

Guidance	Recommendations
Interventional procedures	**Original guidance on Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. NICE interventional procedures guidance 165 (2006).** 1.1 Current evidence suggests there are no major safety concerns associated with interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication, but evidence of efficacy is limited and is confined to the short and medium term. These procedures should only be used in the context of special arrangements for consent, audit and research. 1.2 Clinicians wishing to undertake interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand that the procedure is not curative, and that further surgery may be needed. Patients should be provided with clear written information. In addition, use of the Institute's Information for the public is recommended (available from www.nice.org.uk/IPG165publicinfo). • Audit and review clinical outcomes of all patients having interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine. 1.3 Publication of long-term efficacy data will be useful. The Institute may review the procedures upon publication of further evidence. **Laser lumbar discectomy NICE interventional procedures guidance 027 (2003).** 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.

	Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain NICE interventional procedures guidance 083 (2004). 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. 1.2 Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation 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. • Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 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 **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedures guidance 141 (2005)** 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. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy 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. In addition, use of the Institute's Information for the public is recommended. • 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. **Percutaneous disc decompression using coblation for lower back pain. NICE interventional procedures guidance 173 (2006).** 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.

Prosthetic lumbar intervertebral disc replacement. NICE interventional procedures guidance 306 (2009)
1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated.
1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery.

Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedures guidance 300 (2009).
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 intradiscal electrothermal therapy for lower back pain. NICE interventional procedures guidance 319 (2009)** 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. 1.2 Clinicians wishing to undertake percutaneous intradiscal electrothermal therapy for low back pain 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/IPG319publicinfo). • Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for low back pain (see section 3.1). 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.

Appendix C: Literature search for interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/07/2010	July 2010
Database of Abstracts of Reviews of Effects – DARE (CRD website)	30/07/2010	-
HTA database (CRD website)	30/07/2010	-
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/07/2010	July 2010
MEDLINE (Ovid)	30/07/2010	1950 to July Week 3 2010
MEDLINE In-Process (Ovid)	30/07/2010	July 29, 2010
EMBASE (Ovid)	30/07/2010	1980 to 2010 Week 29
CINAHL (NLH Search 2.0)	30/07/2010	-
BLIC (Dialog DataStar)	30/07/2010	-

Trial sources searched on 02 07 2009 and 04 02 2010:

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 22 06 2009 - 02 07 2009 and 04 02 2010:

- 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

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

1	Spinal Stenosis/
2	(spin* adj3 stenos?s).tw.

3	(lumbar adj3 spin* adj3 stenos?s).tw.
4	LSS.tw.
5	((narrow* or constrict*) adj3 (spin* or lumbar) adj3 canal).tw.
6	((narrow* or constrict*) adj3 (low* or lumbar) adj3 spin*).tw.
7	or/1-6
8	interspinous.tw.
9	IPD.tw.
10	(X-STOP or X STOP).tw.
11	(extension-stop or extension stop).tw.
12	(wallis or minns or coflex or diam).tw.
13	(bioflex system or superion).tw.
14	or/8-13
15	7 and 14
16	Animals/ not Humans/
17	15 not 16