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# Interspinous devices for lumbar stenosis – a review of the literature

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## Abstract

Interspinous process distraction devices are emerging as a treatment for lumbar spinal canal and foraminal stenosis. Lifetime risk is around 10%. The number of patients who could potentially benefit from such surgery is large and is projected to rise. A literature search was undertaken of relevant bibliographic databases, limited to four main languages. High level searching was performed using relevant web-based resources. The literature review indicated that interspinous devices are effective, in the short term, in treating claudication related to spinal stenosis. There was however, a lack of medium and long-term outcome data, particularly with respect to durability of symptom relief and the risks of device migration or dislocation. There was also little published comparison against alternative conventional surgery. Interspinous devices are a promising new technology, the results of longer-term clinical follow-up studies are needed to define more clearly their role in the management of lumbar spinal stenosis.

## BACKGROUND

Lumbar spinal stenosis is primarily a disease of ageing and is defined anatomically by narrowing of the lumbar canal. The lifetime risk has been estimated to be approximately 10% with a slight predominance of women; a very small proportion of cases are caused by congenital narrowing of the spinal canal.<sup>1</sup>

Lumbar non-fusion posterior stabilisation devices are an alternative to decompression surgery or fusion surgery with or without decompression, for the treatment of degenerative conditions of the spine that have failed to respond to conservative treatment. They form an important emerging group of treatment devices. Non-fusion devices may be divided into two main groups — interspinous process distraction devices (IPDDs), also called interspinous spacer devices and pedicle screw systems such as the Dynesys device.<sup>2</sup> IPDDs are inserted between the spinous processes and have no rigid fixation to the vertebral pedicles. There are several kinds of IPPDs available such as the X-Stop (St Francis Medical Technologies; Inc; Alameda, CA), the Wallis® System (Abbott Spine, Austin, TX), the Coflex™ Interspinous Implant (Paradigm Spine, New York, NY) Coflex and the Diam™ Spine Stabilization System (Medtronic, Minneapolis, MN).<sup>2</sup> Most published studies were from use of the X-Spot device and the present report

concentrates on the evidence of effectiveness for this device.

Candidates for the insertion of an IPDD are those with neurogenic claudication due to lumbar spinal canal stenosis and some patients with lumbar radiculopathy due to foraminal stenosis. The importance of appropriate patient selection for the insertion of IPDDs was emphasised by Laurysen,<sup>3</sup> and inadequate description of patient details in the published literature may contribute to the problems of inconsistency with the published evidence.

The X-Stop received CE approval in Europe in 2002 and in the United States in 2005. Between 2002 and 2006 it was reported that 4000 units have been implanted in patients worldwide.<sup>4</sup> The X-Stop is a spinal implant that is inserted between the spinous processes of the symptomatic spinal segment using a minimally invasive procedure that is typically performed with local anaesthetic. The principle is that by preventing extension at the degenerative, symptomatic spinal segment, the load upon these structures is significantly decreased, thereby alleviating the symptoms without altering the healthy, non-symptomatic spinal segments. According to the developer, X-Stop is minimally invasive and no bone is removed, thereby potentially resulting in a faster recovery and rehabilitation and lower complication rates, compared with conventional surgery.<sup>4</sup>

### METHODS

A set of search terms was developed and applied to the following general and specialised health and biomedical databases: Ovid Medline (1950 – Sept 2008), Embase (1980 – Sept 2008), Cochrane Database of Systematic Reviews, British Nursing Index. The search terms used and number of articles identified by each search strategy are shown in the results section (Table 1). Language restrictions were used to limit the literature to articles in French, German, Spanish and English. Each database was searched during September 2008.

An extensive high level search for other relevant literature was undertaken using a previously developed set of web-based sources including: ACP Journal Club EBM reviews, Database of Abstracts of Reviews of Effects, Sumsearch, Google scholar, HMIC, TRIP, UpToDate, National Electronic Library for Health, INAHTA, NICE, National Horizon Scanning Centre. The articles identified were imported into a Reference Manager bibliographic database, scanned and summarised.

The National Research Register, Current Controlled Trials and the Cochrane Central Register of Controlled Trials databases were searched to identify ongoing relevant trials.

### RESULTS

The X-Stop interspinous device has been the subject of four good quality health technology assessments (HTAs)<sub>1 2 4 5</sub>. Of particular importance is the guidance on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication from the National Institute for Health and Clinical Excellence (NICE)<sub>6</sub>. NICE concluded that current evidence did not indicate any major safety issues associated with interspinous devices, but stated that evidence of efficacy was limited. Their review concluded that implant systems may be an alternative to decompression spinal surgery in the unfit or those who choose the less invasive procedure. The specialist advisory group for the guidance questioned, however, the long-term efficacy of the procedure and expressed concerns about additional pain in adjacent levels, device migration, and potential infection. The NICE guidance evidence is limited to the X-spot device and included only 1 case series<sub>7</sub>, and 1 randomised controlled trial.<sub>8 9</sub>

Another important health technology assessment, performed in California in 2006 on the X-Spot device<sub>1</sub>, concluded that use of this device meets the criteria for safety, effectiveness

and improvement in health outcomes, when used in the following population:-

Age > 50 years old

Moderate impairment of physical function

Symptomatic lumbar spinal stenosis at no more than two levels

Relief of symptoms with flexion of the spine

Failure, ≥ 6 months, of non-operative care

No evidence of radiculopathy

Computerised tomography (CT) or magnetic resonance imaging (MRI) evidence of spinal stenosis

The HTA also included the following exclusion criteria:

Prior spinal fusion

Osteoporosis (T-score ≤ -2.5) or metabolic bone disease

Spinal tumour or infection

Morbid obesity (body mass index ≥ 40 kg/m<sup>2</sup>)

A comprehensive review of the evidence, published in 2008<sub>2</sub> in Australia, of the Dynesys, Wallis and X-Stop devices for the treatment of degenerative conditions of the spine found a total of 11 studies on the safety and effectiveness of such devices. Two studies were included that assessed the safety of the X-Stop device (Level III/IV evidence<sub>10</sub>). Minor complications such as respiratory distress, wound swelling and pain occurred in up to 8 per cent of patients, and major complications such as malpositioned implants occurred in up to 3 per cent of patients. One death was reported, which was potentially related to the surgery, in a patient with a history of cardiovascular disease and who postoperatively developed pulmonary oedema. The X-Stop requires a less invasive procedure than either the Dynesys system or fusion surgery, and was associated with lower mean blood loss. Level IV evidence found that the X-Stop resulted in statistically significant improvements on all subscales of the SF-36, although the clinical relevance of these results is unclear. There was a clinically significant improvement in pain in 40–60 per cent of patients who received the X-Stop, while functioning was significantly improved in 10–57% of patients.

In a review of dynamic interspinous process technology, Christie et al.<sub>11</sub> discussed several available spinal implants,

including the X-Stop. The authors state that, although outcomes of patients treated with the X-Stop have been reported as comparable with outcomes of patients treated with laminectomy, a direct comparison, however, between these two methods in a randomised controlled trial (RCT) has not yet been reported.

In another review of interspinous process spacers, Kim and Albert<sup>12</sup> discuss concerns and controversy regarding this technology. The authors stated that interspinous spacer implants are designed to produce increased segmental kyphosis (spinal process flexion) at the treated level, and concern has been raised about the potentially harmful effect of local kyphosis on adjacent segments. Furthermore there are no long-term clinical data regarding the effects of increased kyphosis resulting from placement of interspinous process spacers. The authors also stated that, because the spinous process normally serves as an origin and insertion site for muscles and ligaments, and does not normally act as a compressive load bearing structure, it is possible that compression loading of the spinous processes and cyclic device motion may lead to local tissue changes and pain generation.

Guidelines from the North American Spine Society on the diagnosis and treatment of degenerative spinal stenosis<sup>13</sup> included an evaluation of the X-Stop. The authors concluded that there is insufficient evidence to recommend the X-Stop as treatment and that further research is required.

A number of specific studies are worth examining in greater detail. Lee et al.<sup>7</sup> conducted a small case series of 10 patients to evaluate the safety and efficacy of the X-Stop in elderly patients with lumbar spinal stenosis. Patients were assessed postoperatively by MRI and the Swiss Spinal Stenosis Questionnaire (SSS). There were no complications reported. At a follow up of nine months, 70% of the patients were satisfied with the outcome of the surgery; only one patient, however, showed a significant improvement in physical functioning.

Zucherman et al.<sup>9</sup> conducted a multi-centre RCT to determine the safety and efficacy of the X-Stop in patients with neurogenic intermittent claudication secondary to lumbar spinal stenosis. One hundred patients were randomized to treatment with the X-Stop or nonoperative therapies (n=91). Patients randomised to the control group received at least one epidural steroid injection following enrolment and were prescribed additional epidural steroid injections, nonsteroidal anti-inflammatory medications

(NSAIDs), analgesics and physical therapy as needed. The primary outcome was measured using the Zurich Claudication Questionnaire (ZCQ), a patient-completed validated instrument to evaluate neurogenic intermittent claudication. Assessments were made prior to treatment and at six weeks, six months, one year and two years post treatment, and were based on ZCQ symptom severity and physical function domains and the patient satisfaction domain. Seven patients in the X-Stop group and 10 patients in the control group were lost to follow-up. At each follow-up, patients in the X-Stop group had significantly better outcomes in each domain of the ZCQ. At two years, the X-Stop patients improved by 45.4% over the mean baseline symptom severity score, compared with 7.4% in the control group. The mean improvement in the physical function domain was 44.3% in the X-Stop group and - 0.4% in the control group; 73.1% of patients in the X-Stop group were satisfied with their treatment compared with 35.9% of the control group. Although this study demonstrated positive results, it is difficult to generalise the findings, since the study included a highly selected patient population, those with spondylolisthesis higher than grade one on a scale of one to four were excluded from the study. In addition, the follow-up period was relatively short, and a significant number of patients were lost to follow-up and were not included in the intention to treat analysis. Furthermore by comparing the implant to non-operative treatment in patients who were still symptomatic after 6 months of non-operative treatment (this was a trial inclusion criterion), the positive effect of the implant was shown to be biased. A more suitable control group would have been those receiving conventional surgery. It is, therefore, difficult to use this study as a clear justification for wider use of this procedure.

Kondrashov et al.<sup>14</sup> reported a small case series evaluating the X-Stop in 18 patients. Twelve patients had the X-Stop implanted at either L3–4 or L4–5 levels, and six patients had the device implanted at both L3–4 and L4–5 levels. The mean preoperative Oswestry Disability Index (ODI) score was 45 (range 20–80). At an average follow-up of 51 months (range 45–61 months), the mean ODI score was 15 (range 0–36). Using a 15-point improvement from baseline as the criterion for success, the authors reported that 14 of 18 patients had a successful outcome. It is difficult to draw conclusions from this study because of the small number of patients studied, limited follow-up, and the lack of a control group treated with non-surgical or traditional surgical approaches.

Verhoof et al.<sup>15</sup> reported the outcomes of X-Stop implantation in another case series of 12 consecutive patients with symptomatic lumbar stenosis caused by degenerative spondylolisthesis. All patients had low back pain, neurogenic claudication and radiculopathy. The mean follow-up was 30.3 months. Complete relief of symptoms was observed in eight patients immediately following the procedure, and four patients experienced no improvement. At 12 weeks, two patients who initially had experienced symptom relief experienced a recurrence of pain, neurogenic claudication, and radiculopathy and at 24 months, a third patient experienced a recurrence of symptoms. The implant was removed in the 7 patients with persistent or recurrent symptoms and decompression and posterolateral fusion was performed. The authors stated that because of the high failure rate, they do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis, and that spondylolisthesis should be considered a contraindication for the X-Stop device.

In the UK, Siddiqui et al.<sup>16</sup> conducted a small retrospective study to evaluate the clinical outcome of patients with symptomatic lumbar spinal stenosis treated with X-Stop implantation, and to compare this data with previous studies. Forty consecutive patients were enrolled between January 2003 and December 2006. Two patients were excluded from the study because conversion to surgical decompression was required due to intraoperative fracture of spinous processes during the X-Stop procedure and 1 patient was excluded because of serious comorbidities. Patients were evaluated preoperatively and at three months, six months and one year, using the ZCQ, ODI, and SF-36. Only 24 of 37 patients completed the full set of questionnaires. At a mean follow-up of 12 months, mean ODI scores had improved from 48 to 37, mean ZCQ Symptom Severity scores improved from 3.4 to 2.8, and mean ZCQ Physical Function scores improved from 2.5 to 2.2. Improvements were observed in 5 of the 10 SF-36 sub-scores. The published study does not, however, state whether any of the improvements noted were statistically significant although the sample size suggests that this would not have been the case. The X-Stop was removed in two patients who had dorsally slipped implants at 1 year, with symptoms of neurogenic claudication. Both patients were treated with decompression and fusion. Other centres within the UK are also using the X-Stop and preliminary results have been presented at a conference in 2006, but have not yet been published.<sup>17</sup>

## **DISCUSSION**

In summary, the literature on interspinous devices provides a mixed picture of the efficacy of these devices. There has been relatively little long term follow up or comparison against alternative conventional surgery for the condition. The optimum criteria for the use of these devices is also emerging, but has not yet been fully clarified.

We were unable to identify any published cost effectiveness studies, although some data is available which could be used to compare costs against other treatment options.

There are a number of ongoing trials of interspinous devices. A prospective multi-centre RCT to determine the cost effectiveness of treatment with the X-Stop compared with laminectomy is being performed in the UK and is anticipated to finish in 2010. Two additional multi-centre RCTs of the X-Stop system are being performed in the United States. One of these studies, scheduled to be completed in 2013, will evaluate the safety and effectiveness of the X-Stop device. The other study will compare surgical outcomes of patients treated with X-Stop with outcomes of patients treated with conventional laminectomy. This study began in 2007 and has an estimated completion date of 2011.

There are a number of alternative treatment options which should also be considered in the context of the use of interspinous devices. Traditional treatment for lumbar stenosis includes physical therapy, spinal manipulation and pharmacological therapy (using anti-inflammatory drugs, oral steroids, analgesics and epidural steroid injections) and surgical treatment.<sup>18</sup> Surgical treatments available for lumbar stenosis include laminectomy, with or without spinal fusion and posterior foraminotomy at the involved levels. Conventional surgery can cause complications including wound site infection, haematoma formation, dural tears (with resultant cerebrospinal fluid leaks and risk of meningitis), nerve root damage, the potential for creating postoperative spinal instability, the need for transfusion as a consequence of blood loss, and a range of risks associated with general anaesthetic. In recent years more minimally invasive decompressive techniques have been performed, but again, these surgical options pose a risk for damage to the neural elements.

## **CONCLUSION**

There is considerable interest in the use of IPDDs as a treatment for problems caused by lumbar spinal canal and foraminal stenosis. With the increase in the ageing

population the number of patients suffering from such problems is projected to rise. There are data to support the short-term efficacy of IPDDs to treat claudication related to spinal stenosis. There is however a lack of medium and long-term outcome data, particularly with respect to durability of symptom relief and the risks of device migration or dislocation. Although IPDDs are a promising new technology, the results of longer-term clinical follow-up studies are needed to define more clearly their role in the management of lumbar spinal stenosis. The results of the RCTs being performed currently should add to the evidence on long term effectiveness and cost effectiveness. In the mean time, patients should be enrolled in appropriate research studies rather than operated on as part of routine surgical services.

**LIST OF ABBREVIATIONS**

- CT - Computerised tomography
- HTA – Health technology assessment
- IPDD - Interspinous Process Distraction Devices
- MRI - Magnetic Resonance Imaging
- NICE - National Institute for Health and Clinical Excellence
- NSAIDS - nonsteroidal anti-inflammatory medications
- ODI - Oswestry Disability Index
- RCT – Randomised Controlled Trail
- SSS - Swiss Spinal Stenosis Questionnaire
- ZQC - Zurich Claudication Questionnaire

**Figure 1**

Table 1: Search terms used to identify relevant literature

SEARCH TERMS	RESULTS
1. spin\$.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	653540
2. implant.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	103573
3. exten\$.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	1334341
4. spinal stenosis.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	5394
5. limit 4 to human	5139
6. neurogen\$.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	50146
7. device.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	210524
8. stop.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	53466
9. pain.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	693879
10. back.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	176809
11. vertibr\$.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	16
12. claudication.mp. [mp=ti, ot, ab, hw, kw, nm, tx, sh, ct, tn, dm, mf]	17509
13. 1 or 10 or 11	799513
14. 2 or 7 or 8	356968
15. 6 or 9	740509
16. 5 and 13 and 14 and 15	106
17. 5 and 13 and 14	193
18. remove duplicates from 17	126
19. remove duplicates from 16	68

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spinal stenosis of the lumbar spine. CTAF 2006. Available at: <http://www.ctaf.org/content/general/detail/528>. Accessed 1st September 2008.

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