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Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA
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Horizon Scanning Technology Prioritising Summaries

X STOP® Interspinous Process Decompression System for spinal stenosis

March 2006



ASERNIP(S)

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



Name of Technology:

X STOP® Interspinous Process Decompression System (X STOP®) (St. Francis Medical Technologies, Inc., Alameda, CA, USA)

Purpose and Target Group:

The X STOP implant is indicated for the treatment of patients aged 50 years or older who suffer from pain or neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis. X STOP is intended for those patients with moderately impaired physical function who experience relief from their symptoms of leg/buttock/groin pain, with or without back pain, when bending forward and have undergone a regimen of non-surgical treatment for at least 6 months.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

The X STOP is not listed or registered with the Australian Register of Therapeutic Goods.

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	
United Kingdom		✓	
Japan		✓	
South Africa		✓	
New Zealand		✓	
Turkey		✓	

Impact Summary:

Background

Spinal stenosis refers to the narrowing of the spinal canal anywhere along its axis. Stenosis in the lumbosacral region often results in radicular pain, neurogenic claudication, or both. The degeneration of the vertebral motion segment, consisting of the intervertebral disk and the facet joints, is believed to be the pathophysiologic mechanism involved in the development of stenosis (Vokshoor and Jamali 2005).



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 (Hsiang 2005). Surgical treatment for lumbar stenosis includes laminectomy and posterior foraminotomy at the involved levels. Lumbar laminectomy involves removal of the medial part of the hypertrophic facet joint (Hsiang 2005). This decreases the amount of pressure exerted on the spinal cord, thus relieving the patient from the associated symptoms. Conventional surgery has the potential complications of wound site infection, hematoma formation, dural tears (with resultant cerebrospinal fluid leaks & risk of meningitis), nerve root damage, the potential for creating postoperative spinal instability, the need for transfusion from blood loss as well as risks associated with general anaesthetic (Hsiang 2005).

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. It provides an alternative to conservative treatment and decompressive surgery for patients suffering from neurogenic intermittent claudication (Barclay 2005). 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, which could potentially result in a faster recovery and rehabilitation and lower complication rates, compared to conventional surgery. In addition, the implant is non-fusing, non-destructive and reversible (St. Francis Medical Technologies 2005a).

Clinical Need and Burden of Disease

Narrowing of the lumbar spinal canal is an increasingly common problem that affects 1 in 1000 Americans over 65 years of age (Vokshoor and Jamali 2005). Given that 12% of Australia's current population of 20.5 million are over 65 years of age (Australian Bureau of Statistics 2006), this would translate to approximately 2460 Australians affected by lumbar spinal stenosis.

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The X STOP was developed by St. Francis Medical Technologies, Inc. (Alameda, CA, USA). It received CE approval in Europe in July 2002 and was approved by the US Food and Drug Administration on November 21, 2005. Since then, 4000 units have been implanted in patients worldwide (Omniomix 2005). Based on the burden of disease in Australia and the potential benefits of this device, its uptake will probably be relatively rapid if proven to be safe and effective.



Existing Comparators

- Non-operative treatment: physical therapy, spinal manipulation and pharmacological therapy (using anti-inflammatory drugs, oral steroids, analgesics and epidural steroid injections)
- Surgical treatment: Laminectomy and posterior foraminotomy at the involved levels.
- Interspinous U (Fixano, Péronnas, France)
- DIAM™ Spinal Stabilization System (Medtronic Sofamor Danek, Memphis, TN, USA)
- Wallis® Mechanical Normalization System (Abbott Spine, Inc., Austin, TX, USA) [available in Australia]

Estimated Cost Impact

Costs associated with this product are not available in Australia. However, the cost of an X STOP unit is US\$5,500 (Centers for Medicare and Medicaid Services 2005).

The relevant types of surgery as well as their item numbers, reimbursement fee and number of claims are summarized in the table below.

Table 1 Year 2006 Medical Benefits Schedule of Fees for procedures related to spinal stenosis and laminectomy

Category	Item Number	Benefit	Number of Claims
laminectomy for the removal of intervertebral disc or discs	40300	\$826.50	2194
Intervertebral microsurgical discectomy of disc or discs	40301	\$745.90	2916
laminectomy for recurrent disc lesion or spinal stenosis	40303	\$943.65	2445
laminectomy for spinal stenosis involving more than 1 vertebral interspace	40306	\$1243.05	3963
laminectomy followed by posterior fusions performed by neurosurgeon and orthopaedic surgeon operating together including aftercare	40324	\$497.65	1
laminectomy followed by posterior fusions performed by neurosurgeon and orthopaedic surgeon operating together including aftercare	40327	\$497.65	1
thoracolumbar or high lumbar anterior decompression of spinal cord, not including stabilisation procedure	40351	\$1499.90	22
Spinal fusion (posterior interbody) of 1 level with laminectomy	48654	\$842.90	526
Spinal fusion (posterior interbody) of more than 1 level with laminectomy	48657	\$1172.75	190

Efficacy and Safety Issues

List of Studies Found



Total number of studies	2
Randomised controlled trials	1 (2 papers)
Case series studies	1

The studies included in this summary are highlighted in bold in the reference list. Safety and efficacy data from one randomised controlled trial and one case series study were included in this summary. These studies form the body of evidence currently available on X STOP.

The randomised controlled trial by Zucherman *et al.* (2004; 2005) involved 191 patients, with 100 randomly assigned to undergo X STOP implantation and 91 allocated to a non-operative control treatment that consisted of at least one epidural steroid injection, non-steroidal anti-inflammatory drugs, analgesics and physical therapy. At the completion of the study, data from 93 patients from the X STOP group and 81 patients from the control group were analysed (7 X STOP patients and 10 control patients were lost to follow up). Patient outcomes were assessed using the Zurich Claudication Questionnaire (ZCQ) at 6 weeks, 6 months, 1 year and 2 years post-surgery. Three distinct parameters were covered with the ZCQ: symptom severity, physical function and post-treatment patient satisfaction.

The study demonstrated considerably greater efficacy for X STOP over the traditional non-operative treatment for neurogenic intermittent claudication. Over a 2 year follow-up period, Zucherman *et al.* (2004; 2005) recorded the following results: 60.2% (56/93) of patients in the X STOP group indicated an improvement in symptom severity, compared with 18.5% (15/81) of patients in the control group ($p < 0.001$); 57.0% of the X STOP group (53/93) recorded an improvement in physical function, compared with 14.8% of the control group (12/81) ($p < 0.001$): and 73.1% (68/93) of the X STOP group were somewhat satisfied with their treatment, compared with 35.9% of control patients (28/78) ($p < 0.001$). Six patients in the X stop group and 24 patients in the control group underwent decompressive surgery (laminectomy) for unresolved stenosis symptoms during the 2 year follow up period – while the need for surgery rate was higher in the control group compared to X Stop group the fact that 6/93 (6.5%) X STOP patients required laminectomy is substantial. The predictors of success for the X STOP were a positive femoral stretch test, ($p < .01$) the absence of comorbid conditions ($p < .013$) and low surgical blood loss ($p < .007$).

The case series study by Siddiqui *et al.* (2005) assessed the effect of X STOP implantation on the lumbar spine (specifically vertebral canal and intervertebral foraminal dimensions) in vivo with magnetic resonance imaging (MRI). A total of 12 patients with lumbar spine stenosis and neurogenic intermittent claudication (as confirmed on supine MRI) who were unresponsive to non-operative treatment were enrolled for this study. The patients received preoperative positional MRIs (T2 parasagittal and transverse sequences) through the 5 lumbar discs prior to X STOP implantation in 5 specific positions: erect (standing), neutral



sitting, sitting in flexion, sitting in extension and supine. After the implantation, patients were reviewed at 6 and 12 weeks and had a second series of positional MRIs at 6 months to measure the encroachment of soft tissue and bone on the exit foraminae.

Comparison of data from pre- and postoperative flexion to extension revealed that the left exit foramina decreased by 31.2% (preoperative) and 14.1% (postoperative), while the right exit foramina decreased by 18.3% (preoperative) and 9.4% (postoperative). When the patient moved from flexion to standing, the dural sac area was decreased by 26.7% preoperatively and 18.1% postoperatively; from flexion to extension it was decreased by 20.3% preoperatively and 5.9% postoperatively; and from neutral to standing it decreased by 16.5% preoperatively and 13.8% postoperatively (Siddiqui *et al.* 2005). Also, comparing areas pre- and postoperatively in extension, the left and right exit foramina increased by 34.2% ($p < 0.002$) and 25.4% ($p < 0.002$), respectively. Similarly, the increase in dural sac area by 20% on standing ($p < 0.006$), 16.3% in neutral position ($p < 0.006$) and 26.9% in sitting was statistically significant (Siddiqui *et al.* 2005). These results indicated that the X STOP was successful in reducing spinal canal compression, an outcome that reduces clinical symptoms of lumbar stenosis.

In terms of safety data, Zucherman *et al.* (2005) did not observe any device-related intraoperative complications and no conversions to laminectomy were necessary during the procedure. However, there were three device-related postoperative complications in the X STOP group. One patient suffered X STOP dislodgement after a fall; another patient was diagnosed with an asymptomatic spinous process fracture at 6 months' follow up; and the third patient experienced worsening pain 382 days after treatment. In addition to this, one device malposition was identified. In terms of the comparator group, five complications were associated with the epidural injection, with one patient unable to tolerate it, one patient having a severe flare in symptoms needing admission, two patients experiencing leg paresthesias and one patient seeking treatment at an emergency room for back pain 6 hours following the injection. Finally, one patient suffered a heart attack 3 days after treatment but it is unknown whether this was related to the injection procedure. Distraction was maintained in 96% of the levels implanted with the X STOP. There was no detectable difference between the X STOP patients and the controls with respect to radiographic spine measurements at the 1 and 2 year assessments.

In terms of safety data from the Siddiqui *et al.* (2005) study, placement of the X STOP did not have a significant impact on the alignment of the spine, with the overall range of spinal movements being preserved. The study found that the total lumbar angles in flexion and extension were not significantly altered, and that the minor changes in the alignment of the endplates were not statistically significant.

Ethical Issues

No issues were identified from the retrieved material



Cultural or Religious Considerations

No issues were identified from the retrieved material

Other Issues

The only randomised controlled trial available thus far was conducted by James Zucherman and Ken Hsu. Both researchers are inventors of the X STOP and have served on the Medical Board of St. Francis Medical Technologies, Inc. (St. Francis Medical Technologies 2005b).

The trial conducted by Zucherman *et al.* (2004) also chose an inappropriate control group for the purposes of the study as the insertion of the implant, effectively surgery, was compared with non-operative therapy rather than comparing one surgical technique with another. By comparing the implant to traditional non-operative treatment in patients who were still symptomatic after 6 months of non-operative treatment (which was an inclusion criteria for the RCT) this in effect portrayed the implant in a more favourable way than perhaps if it had been compared to traditional surgery for lumbar stenosis.

The case series by Siddiqui *et al.* (2005) provided important information regarding the X STOP, but had a very small sample size.

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:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

Note: MSAC has commissioned full HTA.

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network of Agencies for Health Technology Assessment, relevant online journals and the Internet was conducted in January 2006.

Search terms used were:

X stop, X-stop, lumbar stenosis, interspinous implant, interspinous process decompression, St Francis Medical Technologies.

This Horizon Scanning Prioritising Summary was prepared by Mr Mario Zotti from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).