



**AN INTERSPINOUS PROCESS DISTRACTOR (X STOP) FOR THE
TREATMENT OF SPINAL STENOSIS OF THE LUMBAR SPINE
A Technology Assessment**

INTRODUCTION

The California Technology Assessment Forum has been asked to update its review of the scientific literature on the safety and efficacy of an interspinous process distractor (X STOP) for the treatment of symptoms arising from spinal stenosis of the lumbar spine.

BACKGROUND

Spinal Stenosis

Lumbar spinal stenosis is primarily a disease of aging defined anatomically by narrowing of the lumbar canal. It most commonly presents in the sixth or seventh decade of life. The lifetime risk has been estimated to be approximately 10% with a slight predominance of women. A much smaller proportion of cases of spinal stenosis are caused by congenital narrowing of the spinal canal. The classic symptoms of lumbar spinal stenosis are lower back and leg pain that come on with walking and are relieved by sitting down or bending forward.

A number of degenerative processes usually combine to decrease the size of the spinal canal at the affected level. These include bulging of the intervertebral disc, hypertrophy of the ligamentum flavum, facet joint hypertrophy with bone spurring and spondylolisthesis. This is thought to lead to chronic compression of the nerve roots causing decreased blood flow, ischemia and local edema. Forward flexion of the spine increases the cross-sectional area of the spinal canal, decreases compression and relieves symptoms.¹

The natural history of lumbar spinal stenosis has not been well studied. One investigator followed 32 patients for four years. By self-report with a visual analog scale (VAS) for symptoms, some patients improved (15%), some worsened (15%), but most (70%) had stable symptoms. By physician exam, 41% improved, 18% worsened and 41% were unchanged. Several other studies have documented that a large

proportion of patients have stable symptoms for many years and do not need to rush to surgical intervention.^{2,3}

Conservative treatments for lumbar spinal stenosis include physical therapy, lumbar corsets, non-steroidal anti-inflammatory drugs, opioid analgesics and epidural steroid injections. Surgical decompression appeared to be the logical treatment for spinal stenosis. Indeed, spinal stenosis has become one of the most common indications for spinal surgery with an eight-fold increase in incidence over 13 years.³ However, many patients do well with conservative treatment^{2, 4, 5} and surgical decompression has not been well studied, particularly with direct comparison to non-surgical treatments.⁶

Lumbar Laminectomy for Spinal Stenosis

The clinical trial evidence supporting use of decompressive laminectomy for lumbar spinal stenosis is weak. An oft-cited systematic review and attempted meta-analysis⁷ found no randomized trials comparing laminectomy to conservative therapy. The 74 studies evaluated were primarily single center retrospective case series. The reported “success rate,” defined as good to excellent results by a number of different measures, ranged from 26% to 100% (average 64%) with mean follow-up less than four years. Wide decompressive laminectomy has been the standard procedure, though recently less invasive surgical approaches have been tried.^{8, 9} A recent systematic review found data suggesting that laminectomy alone had better results than laminectomy plus either instrumented or non-instrument fusion. However, selection bias could explain these results as they were not based on randomized comparisons. Since that time, several randomized trials have been published. These were summarized in a recent Cochrane review.⁶ The authors concluded that there was no clear evidence about the most effective technique for surgical decompression for spinal stenosis. They also found one small randomized trial directly comparing fusion to conservative treatment.² In the study, 31 patients with moderate symptoms of spinal stenosis were randomized to surgical treatment (n=13) or conservative treatment (n=18). No specific therapy was given to the conservatively treated group other than “back school.” Ten of the patients randomized to conservative treatment (55%) crossed over to surgery during the first four years of follow-up. Results were good for 47% of patients in the conservative arm after four years compared to 92% of patients treated with surgery. The study has been criticized for the lack of a structured physical therapy program designed to treat spinal stenosis. Studies have been unable to identify patient characteristics that predict who is likely to respond best to surgery and who will respond to conservative management.² A recent prospective case series reported clinically meaningful improvements in 73% of patients receiving focused physical therapy.⁵ Only

two out of 57(4%) patients in this study went on to surgery during an average follow-up period of 16 months. Thus, the benefits of laminectomy over the best conservative management remain unclear.

X STOP Interspinous Distractor

The X STOP Interspinous Distractor is an oval titanium spacer that is inserted between adjacent spinous processes at the level of spinal stenosis. It is designed to slightly flex the affected level in order to increase the cross-sectional area of the vertebral canal and the intervertebral foramina. It also prevents extension, thus preventing nerve root impingement and relieving the symptoms of lumbar spinal stenosis.

The X STOP is inserted without attachment to the bone or ligaments. The device is an oval spacer that swivels, allowing it to self-align with the uneven surface of the spinous process. No sharp edges come into contact with the spinous process and compressive loads are distributed equally on the surface of the bone. Lateral wings prevent forward and side-to-side movement and the intact supraspinous ligament prevents posterior displacement.

Cadaveric studies demonstrated that implantation of the X STOP device prevents narrowing of the spinal canal and foraminal area during extension without significantly impacting range of motion during axial rotation.¹⁰⁻¹² It also reduces the pressure in the intervertebral discs and facet joints at the affected level.^{13, 14}

The device is most commonly implanted under local anesthesia with the patient lying flexed in the lateral decubitus position. The procedure is designed to minimally disrupt adjacent soft tissue such as the paraspinal muscles and the supraspinous ligament. A 4-5cm midline incision is made over the spinous processes of the affected segments. A curve dilator is inserted at the anterior margin of the interspinous space for placement of the device. The goal is to keep the supraspinous and interspinous ligaments intact. An appropriately sized spacer is then inserted and an adjustable wing is fastened to the device to secure it into place. The incision is then closed.

The device is being marketed as a minimally invasive alternative to laminectomy in patients with moderate symptoms of lumbar spinal stenosis who have failed at least six months of conservative therapy. Patients with severe symptoms would be considered candidates for laminectomy and would not be eligible for the device.

Technology Assessment (TA)

TA Criterion 1: The technology must have the appropriate regulatory approval.

The U.S. Food and Drug Administration (FDA) approved the X STOP® Interspinous Process Decompression System (St. Francis Medical Technologies, Inc., Alameda, CA) through the Pre-market approval (PMA) process on November 21, 2005. The X-Stop Interspinous distractor is indicated for the treatment of patients 50 years and older who have moderately impaired physical function from back and leg pain caused by spinal stenosis and who have obtained little or no pain relief after at least six months of non-surgical treatments such as pain medications, physical therapy, injections and/or manipulation.

The X STOP may be referred to as an Interspinous distractor.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words X STOP or spinal stenosis/surgery. These were cross-referenced with the keywords lumbar and human. The search was performed for the period from 1966 through April 2006. The bibliographies of systematic reviews and key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

The literature search identified three small case series¹⁵⁻¹⁷ and several publications describing one randomized clinical trial.^{18, 19} The controlled clinical trial had adequate power to evaluate differences in health outcomes relevant to patients suffering from symptoms associated with spinal stenosis.

Level of evidence: 1 and 5

TA Criterion 2 is met.

TA Criterion 3: The technology must improve the net health outcomes.

There are a number of patient-centered clinical outcomes commonly used to assess response to spinal procedures. These include the proportion of patients with successful overall outcomes by self-report, improvement in pain measured on a validated pain scale (usually a 10-point VAS) and improvements in function using a validated scale like the Oswestry low back pain Disability Index (ODI). Other important outcomes include the proportion of patients returning to work and the proportion of patients who no longer require narcotic pain medications. These were not systematically used in the studies described below.

The pivotal trial used the Zurich Claudication Questionnaire (ZCQ); also known as the Brigham Spinal Stenosis scales (BSS), as their primary set of outcome measures. The questionnaire includes three scales with seven questions on symptom severity, five on physical function and six on patient satisfaction. The three domains of the questionnaire were developed by a team of psychometricians, spine surgeons, rheumatologists and physical therapists to be used independently in a large, prospective study on the outcomes of surgery for lumbar spinal stenosis.^{20, 21} The instrument's internal consistency, test-retest reliability and responsiveness to intervention have been validated in a prospective study.^{22, 23} Validation studies found that the minimum clinically important difference on the Symptom and Function Scales was approximately 0.5 points.²⁴

Case Series

Lee et al.¹⁶ reported their initial experiences in 10 consecutive cases in Japan.¹⁶ The patients were required to be at least 60 years old and to have mild to moderate symptoms of spinal stenosis confirmed by magnetic resonance imaging (MRI) with pain that increased with extension and was relieved with flexion. They were followed for a mean of 11 months. The average operative time was 20 minutes and blood loss did not exceed 100 ml. All patients received general anesthesia. They had no intraoperative or device related post-operative complications. Using the ZCQ, four patients had significant improvements in symptom severity, one patient had significant improvements in physical function and seven patients were at least somewhat satisfied with the outcome of the surgery. The average dural sac area increased 23% (from 74 mm² to 90 mm², p<0.002) and the intervertebral foraminal area increased 36% (from 60 mm² to 82 mm², p<0.0005). This is a small case series reporting only modest clinical improvements without any controls for comparison.

The anatomic data are intriguing and support the findings of the cadaveric studies, but randomized trials are needed.

Siddiqui et al.¹⁷ also reported on a small case series of 12 patients in Scotland.¹⁷ The patients all had not responded to conservative treatment and had symptomatic spinal stenosis confirmed by MRI at one or two levels. They were required to be at least 50 years old and be able to sit for at least 50 minutes without pain. The investigators excluded patients with cauda equina syndrome, pathologic spinal fractures, severe osteoporosis, body mass index > 40 kg/m² or Paget's disease. The study primarily reported on changes in MRI measurements from before the procedure to six months after the procedure. Patient specific outcomes were not reported. The average dural sac area increased 20% (from 78 mm² to 93 mm², p=0.006) and the intervertebral foraminal area increased 30% (average increase of 26 mm² at left foramina and 23 mm² at right foramina, p<0.002 for both). There was also a significant increase in the disc height when standing at the affected level (p<0.006). These in vivo anatomic improvements support the hypothesis that the X STOP has the potential to provide symptomatic relief from pain caused by compression of neural elements. However, no patient-centered outcomes were reported in the study.

Heijnen and Kramer published a retrospective case series on the outcomes of 14 patients treated with a total of 24 X STOP implants in Holland.¹⁵ There were six men and eight women who ranged in age from 53 to 80 years. Patients were required to have leg pain that was relieved with sitting or bending forward. Spinal stenosis was confirmed with MRI imaging. The average length of surgery was 20 minutes and the estimated blood loss was always less than 50 ml. There were no peri-operative complications, although one patient died during the first three months "of a non back-related cause." The authors did not use any standard instrument to assess patient outcomes. The average pain declined from nine pre-operatively to three post-operatively on a non-standard scale ranging from 1 to 10. The majority of patients (11/13) reported being very satisfied with the procedure.

The case series data are promising. The anatomic improvements demonstrated in prior cadaveric studies were confirmed in vivo. Patients also reported improvements in pain, function and satisfaction with the procedure although standard validated instruments were not used and there is often a large placebo effect on self-reported measures after patients undergo a surgical procedure. Larger studies with validated outcome measures and control groups are needed to confirm that these results translate into clinically meaningful outcomes for patients.

Randomized Clinical Trials

There have been at least three publications documenting the results of the pivotal clinical trial for the X STOP after one, two, and four years of follow-up.^{18, 19, 25} Unfortunately, the four year data report results for a subset of 15 patients randomized to receive the device without any follow-up of the non-operative controls for comparison. Thus, the main comparisons are limited to a maximum of two years of follow-up.

The study randomized 200 patients at nine centers to receive either the X STOP device or conservative management including epidural steroid injections. Unfortunately, nine patients randomized to the non-operative arm of the study, withdrew at randomization because they entered the study hoping to be randomized to the device. No attempt was made to blind investigators or patients and it is not clear whether allocation concealment was attempted. The inclusion criteria included age greater than or equal to 50 years with leg, buttock or groin pain relieved by flexion who had failed at least six months of non-operative therapy. Patients had to be able to sit for 50 minutes without pain and walk at least 50 feet. Lumbar spinal stenosis was documented by CT or MRI at one or two levels. Patients were excluded if they had a fixed motor deficit, cauda equina syndrome, significant lumbar instability, prior lumbar surgery, significant peripheral neuropathy, greater than 25° of scoliosis, more than grade 1 spondylolisthesis at the affected level, severe osteoporosis, pathologic fractures, Paget's disease, recent steroid use, obesity or active infection or systemic disease.

The primary outcome used in the study was the ZCQ, a validated instrument with three domains: symptoms severity, physical function and post-treatment patient satisfaction.^{22, 23} The best score in each domain is 1, representing no pain, no limitation in physical function and very satisfied with the treatment results. The investigators defined clinical success as a patient satisfaction of at least 2.5 (somewhat satisfied) and at least a 0.5-point improvement in both symptom severity and physical function. Patients also completed the Medical Outcomes Study Short Form-36 (SF-36). Outcomes were assessed at six weeks, six months, one year and two years following treatment.

Even though nine patients in the non-operative arm dropped out at randomization, the authors report patient demographics on the original 200 patients randomized. The average age was 69 years and 54% were male. The duration of pain was 33% longer in the non-operative group (4.7 vs. 3.5 years, p not reported). Fewer patients in the non-operative group had received prior treatment with epidural steroid injections (48% vs. 64%, p=.02 by my calculation).

In the X STOP arm, 64 patients received one implant and the remaining 36 received two implants. The most common levels were L4/L5 (65%) and L3/L4 (32%). The procedure took an average of 54 minutes and was performed under local anesthesia for 97 out of 100 patients. The estimated blood loss was 46 ml. Most patients (96/100) went home in less than 24 hours.

There was significantly more loss to follow-up in the non-operative group at each time point. At the six-week evaluation, 6% of the X STOP group and 28% of the non-operative group did not complete the questionnaire assessments. At the one-year evaluation, 12% of the X STOP group and 32% of the non-operative group had incomplete data. The primary reasons for incomplete data included in the study were laminectomy (10%) and withdrawal from the study (7.5%). Two patients in each group died during the first year of follow-up and two patients had their implant removed. Three patients in the X STOP group and 17 patients in the non-operative group had laminectomy. An additional three patients in the X STOP group and 12 patients in the non-operative group withdrew from the study. Patients who had the implant removed, went on to laminectomy or withdrew from the study were considered treatment failures. At the two-year follow-up, 93 out of 100 of the patients in the X STOP arm and 81 out of 100 of the non-operative arm had data for analysis. At that time in the X STOP arm, seven patients were lost to follow-up, one patient withdrew, two did not complete the ZCQ and four patients had died. In the non-operative arm, 10 patients were lost to follow-up, 16 patients withdrew and three patients had died. At two years, six patients in the X STOP arm and 24 patients in the non-operative arm had laminectomy for unresolved symptoms.

Pre-treatment scores for the symptom severity domain of the ZCQ (X STOP 3.14 vs. 3.12 non-operative) and physical function domain (2.48 vs. 2.49) were similar in the two groups. Large differences in the scores of the three domains of the ZCQ were apparent at the six-week evaluation and remained stable in both groups over the first year of follow-up. All of the data were presented graphically and no p-values were reported, except that they were statistically significant. Approximately 75% of patients randomized to X STOP had improvements in symptom severity compared with approximately 30% of non-operative patients. Initially 61% (60/99) of patients in the X STOP arm reported severe to very severe pain, as did 60% (53/88) in the non-operative arm. After one year of follow-up 64% (57/89) of patients in the X STOP arm reported no or mild pain, compared to only 21% (16/78) of patients in the non-operative arm. Note that the changing numbers in the denominators and the inconsistency with the reported number of patients completing the ZCQ at one year (88 and 68 respectively in Table 2 vs. 99 and 88 in Table 6 in the article presenting the 1 year results) make interpretation of these statistics difficult. At two years, the investigators report that the symptom severity scores had improved by 45% in the X STOP arm and by 7.4% in the non-operative arm

($p < 0.001$). A clinically significant improvement in symptom severity was reported by 60% (56/93) of patients in the X STOP arm compared with 19% (15/81) in the non-operative arm ($p < 0.001$). At one year of follow-up, approximately 65% of patients randomized to X STOP had improvements in physical function compared with approximately 20% of non-operative patients. At two years, the physical function score improved by 44% in the X STOP arm and declined by 0.4% in the non-operative arm, with 57% versus 15% reporting clinically significant improvements respectively. For the primary endpoint, satisfaction with treatment and significant improvement in symptom severity and physical function, approximately 60% of patients who received the X STOP were considered a clinical success at one year of follow-up compared with approximately 10% of patients in the non-operative group. At two years, the percentages were 48% in the X STOP arm and 5% in the non-operative arm. If all patients in the X STOP arm without complete follow-up are considered failures and all patients in the non-operative arm are considered successes, the success rate would be 45% (45/100) in the X STOP arm and 17% (17/100) in the non-operative arm ($p < 0.0001$, my sensitivity analysis). The authors also reported large clinically and statistically significant improvements in all eight domains of the SF-36 in the X STOP arm compared with the non-operative arm. For example, the physical function domain increased from 32 to 62 in the X STOP arm, but only from 33 to 43 in the non-operative arm.

One site of the randomized trial reported four-year data using the ODI. The average ODI score decreased from 43 to 14. Using the standard definition of a significant improvement in the ODI (15 points), 80% (12/15) of the patients had successful outcomes. These results are encouraging, but they represent a subset of data from one center with no control group. It would be helpful if the investigators would report ODI scores for all patients randomized to the X STOP and the control arms.

There were many methodological problems with the randomized clinical trial. The immediate drop out of patients randomized to the non-device arm suggests a poor informed consent process as patients should have been aware of the likelihood of randomization to the non-intervention arm and of the importance of remaining in the study. Given the immediate differential drop out, the primary benefit of randomization, equal distribution of unmeasured confounders in both arms of the study, was likely lost if they are excluded from the analysis. For the primary outcome, all of these patients were included in the analysis, but considered failures. This clearly biases the results against the non-operative group. Additionally, this clear evidence of biased expectations of patients recruited for the study also makes the lack of blinding much more important for patients remaining in the study. Since the primary outcomes of the study were patient self report of symptoms, patients who were disappointed by their randomization to the control arm were likely to report

worse outcomes than those who knew they received the device. A better study design would have included taking all patients to the operating room, performing an incision on all patients and only then unblinding the performing surgeon. Patients randomized to the sham arm could have received their epidural injection during the procedure.

The conservative therapy delivered to the control arm was not standardized and may not have been state of the art. A comprehensive approach including physical therapy focusing on flexion exercises and activity modifications in addition to the steroid injections would have been a more convincing control group intervention.^{5, 8, 26}

Harms

In the X STOP arm, one each of the following complications occurred: respiratory distress, coronary ischemia, pulmonary edema, wound dehiscence, hematoma and incisional pain. The patient with pulmonary edema developed symptoms two days after the procedure and subsequently died. During two years of follow-up, there were also four device related complications. One patient fell and dislodged the device – it was removed without complication. One patient was noted to have an asymptomatic spinous process fracture on routine x-rays at the six-month follow-up. One implant was malpositioned and one patient had worsening pain one year after the procedure that was thought to be due to the implant. The X STOP device was removed without complication.

Summary

The uncontrolled case-series data support the potential effectiveness of the X-STOP for lumbar spinal stenosis. Unfortunately, the pivotal trial has significant methodological issues due to the lack of blinding and the immediate drop out of nine patients randomized to the non-operative arm. However, the outcomes were strongly in favor of the X STOP arm. In hypothetical sensitivity analyses in which all patients that dropped out or were lost to follow-up in the control arm were considered successes, the success rate for the X STOP arm was 20% to 30% higher than that for the control arm on each of the individual ZCQ scales and on the composite success outcome. The improvements seen in the X STOP arm were statistically and clinically important in this sensitivity analysis. This analysis cannot account for possible bias in the patient's self-assessment of outcomes due to lack of blinding. However, the stability of the results at 6, 12 and 24 months suggests that this may not be a significant source of bias: the impact on outcomes due to some patients' positive response to randomization to the X STOP arm and other patients' disappointment due to

randomization to the control arm would likely decrease over time. Finally, the risks associated with implantation of the device and living with the device appear small, although the number of patients examined is small. On balance, the benefits of the device appear to outweigh the harms in this population.

TA Criterion 3 is met.

TA Criterion 4: **The technology must be as beneficial as any established alternatives.**

The standard treatment for patients with lumbar spinal stenosis that does not respond to conservative measures is laminectomy with or without fusion at the affected levels, although the evidence supporting this is weak. There are no studies directly comparing use of the X STOP to laminectomy. However, the authors of the pivotal clinical trial provided some data.¹⁹ They compare their own two-year follow-up outcomes to the results of the 28 patients in their study who later elected to undergo laminectomy to the results from a clinical trial that used the ZCQ to assess the efficacy of laminectomy in patients with spinal stenosis in 197 patients with two-year follow-up data^{24, 27} and to a second cohort by Fokter et al.²⁸ that also used the ZCQ in 58 patients with an average of 27 months follow-up after laminectomy (See Table below).

Table: Comparison of X STOP results to laminectomy using the Zurich Claudication Questionnaire

	X STOP (n=96)	Laminectomy in Zucherman trial (n=28)	Laminectomy in Katz trial (n=197)	Laminectomy in Fokter trial (n=58)
Symptom severity, % with significant improvement	58	57	64	64
Physical function, % with significant improvement	55	64	59	55
Patient satisfaction, %	71	54	72	59
Overall success, %	47	43	47	43

Thus, it appears that the results achieved with the X STOP were comparable to those reported for laminectomy. However, there may be significant selection bias influencing these results. It may be that patients in the trial by Katz et al.²⁷ had patient characteristics that would predict worse outcomes than those expected for patients in the X STOP trial. Certainly, those patients in the X STOP trial who elected to have a laminectomy during the two years of follow-up were likely to have more significant disease than those who did not require laminectomy.

Insertion of the X STOP is not without risks as noted in the harms section under TA criterion 3 above. However, they are certainly lower than the risks associated with laminectomy. In Turner's systematic review,⁷ there was a 13% overall rate of complications for laminectomy that included a 0.3% peri-operative mortality, 6% dural tears, 3% infection and 3% deep venous thrombosis. The X STOP procedure also can be done in less time with significantly less blood loss.

In summary, the X STOP results appear better than those of conservative management and may be comparable to those achieved by laminectomy, although a randomized equivalence trial would be required to demonstrate the latter hypothesis. Given the lack of randomized clinical trial evidence supporting the efficacy of laminectomy for the treatment of lumbar spinal stenosis and patient selection criteria aimed at patients with symptoms not severe enough to warrant surgery, the control group used in the trial was appropriate. It would now be useful to randomize patients with more severe symptoms to either X STOP or laminectomy in order to evaluate whether the current results could generalize to patients currently treated with laminectomy.

TA Criterion 4 is met.

TA Criterion 5: **The improvement must be attainable outside the investigational setting.**

The surgical procedure is not technically difficult and similar results should be obtainable by any spinal surgeon who has received training comparable to that offered by the manufacturer. The FDA has required that the company conduct a five-year post-marketing study of 240 patients at multiple institutions with annual assessment using the ZCQ as well as the ODI, a standard VAS for pain and the SF-36. These data will be helpful in further evaluating the effectiveness of the X STOP device outside the investigational setting.

TA Criterion 5 is met.

CONCLUSION

The X STOP interspinous process distractor is designed to treat lumbar spinal stenosis with a minimally invasive surgical procedure. A titanium spacer is placed between the spinous processes of two vertebrae at the affected level. A systematic search of the literature located three case series and one randomized trial. Both cadaveric and case series data suggested that implantation of the device increases the cross sectional area of the spinal canal and neural foramina while reducing intervertebral disc and facet joint pressure. There is a reduction in extension at the level of the device, but no reduction in flexion, lateral bending or axial rotation. Unfortunately, the one randomized trial has significant methodological issues. Apparently, there was no allocation concealment and no attempt to blind patients or staff, even for a short period of follow-up. Nine patients randomized to the non-operative arm dropped out of the study once they learned of their randomization status. Because the primary outcomes of the study are subjective, those results may be biased because of positive expectations for patients randomized to the device and negative expectation for patients randomized to conservative management. Additionally, the conservative management was not carefully defined and operationalized at each site. Patients in the non-operative arm may not have received physical therapy and other therapies according to the best available evidence for management of spinal stenosis. However, the outcomes were strongly in favor of the X STOP arm. Sensitivity analyses designed to maximize bias against the device still gave results that were strongly in favor of the device. The improvements seen in the X STOP arm were statistically and clinically important in this sensitivity analysis. This analysis did not account for possible bias in the patient's self-assessment of outcomes due to lack of blinding, but, the stability of the results during follow-up makes it unlikely that bias from unblinding explains the difference in outcomes. Finally, the outcomes in the device arm appeared comparable to those achieved in prospective studies evaluating the efficacy of surgical procedures for lumbar spinal stenosis.

DRAFT RECOMMENDATION

It is recommended that the use of the X STOP interspinous process distractor device meets Technology Assessment Criterion 1 through 5 for safety, effectiveness and improvement in health outcomes when used in the following patient 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
- Failed ≥ 6 months of non-operative care
- No evidence of radiculopathy
- CT or MRI evidence of spinal stenosis

Exclusion criteria

- Prior spinal fusion
- Osteoporosis (T-score ≤ -2.5) or metabolic bone disease
- Spinal tumor or infection
- Morbid obesity (body mass index ≥ 40 kg/m²)

The California Technology Assessment Forum panel voted unanimously in favor of this recommendation.

June 21, 2006

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center Medical Advisory Panel has not reviewed this technology.

Centers for Medicare and Medicaid Services (CMS)

CMS does not have a specific coverage determination noted for this technology. There is however a Tracking Form for Applicants for New Technology Add-on Payments which addresses the use of X STOP.

California Association of Neurological Surgeons (CANS)

CANS was invited to provide an opinion on the use of this technology and to participate in the meeting.

California Orthopaedic Association (COA)

COA provided an opinion on the use of this technology in favor of the recommendation. A representative was not able to attend the meeting.

Spine Arthroplasty Society (SAS)

SAS was invited to provide an opinion on the use of this technology and to participate in the meeting.

ABBREVIATIONS USED IN THIS ASSESSMENT:

MRI: Magnetic Resonance Imaging

ZCQ: Zurich Claudication Questionnaire

VAS: Visual Analog Scale

ODI: Oswestry Disability Index

BSS: Brigham Spinal Stenosis

SF-36: Medical Outcomes Study Short Form-36

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