A Multicenter, Prospective, Randomized Trial Evaluating the X STOP Interspinous Process Decompression System for the Treatment of Neurogenic Intermittent Claudication

Two-Year Follow-Up Results

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Study Design. A randomized, controlled, prospective multicenter trial comparing the outcomes of neurogenic intermittent claudication (NIC) patients treated with the interspinous process decompression system (X STOP) with patients treated nonoperatively.

Objective. To determine the safety and efficacy of the X STOP interspinous implant.

Summary of Background Data. Patients suffering from NIC secondary to lumbar spinal stenosis have been limited to a choice between nonoperative therapies and decompressive surgical procedures, with or without fusion. The X STOP was developed to provide an alternative therapeutic treatment.

Methods. 191 patients were treated, 100 in the X STOP group and 91 in the control group. The primary outcomes measure was the Zurich Claudication Questionnaire, a patient-completed, validated instrument for NIC.

Results. At every follow-up visit, X STOP patients had significantly better outcomes in each domain of the Zurich Claudication Questionnaire. At 2 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. In the X STOP group, 73.1% patients were satisfied with their treatment compared with 35.9% of control patients.

Conclusions. The X STOP provides a conservative yet effective treatment for patients suffering from lumbar spinal stenosis. In the continuum of treatment options, the X STOP offers an attractive alternative to both conservative care and decompressive surgery.

Key words: prospective randomized study design, lumbar spinal stenosis, neurogenic intermittent claudication, epidural injection, laminectomy, interspinous process decompression. Spine 2005;30:1351–1358

Studies evaluating neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis (LSS) indicate that 3 to 4% of patients with low back pain who see a general physician have LSS, and 13 to 14% of patients with low back pain who see a specialist have LSS.1–4 The cost to society of NIC resulting from medical care, loss of productive work hours, legal costs, and compensation costs is in the tens of billions of dollars in the United States annually.5,6 The definition, etiology, clinical symptoms, incidence, and treatment of NIC have been well documented and are generally attributed to neural compression at one or more lumbar motion segments.7–22

The characteristic symptoms of NIC such as back and leg pain, tingling, numbness, and weakness are generally present depending on the patient’s posture, with symptoms exacerbated in positions of lumbar extension such as standing and walking, and relieved in positions of flexion such as sitting or bending forward.8,12,17,19–21,23–25 The primary level affected is L4–L5, followed by L3–L4, L5–S1, L2–L3, and L1–L2.14,15,17,22,26 Patients with stable symptoms are treated with a regimen of nonoperative therapy that may include epidural steroid injections, oral steroids, nonsteroidal anti-inflammatory medication, analgesics, physical therapy, and spinal manipulation. The only treatment option available to patients who fail to respond to these therapies is decompressive surgery, such as a laminectomy, which may be accompanied by a fusion. The success rate of decompressive surgery as re-
ported in the clinical literature is quite variable, and the procedure is associated with a relatively high complication and reoperation rate.\textsuperscript{27–32} Turner’s meta-analysis of 74 published studies of surgery for lumbar spinal stenosis found good to excellent results ranging from 26 to 100\%.\textsuperscript{33}

The interspinous process decompression system (X STOP) provides an alternative therapy to conservative treatment and decompressive surgery for patients suffering from NIC.\textsuperscript{34} The X STOP is implanted between the spinous processes and reduces pathologic extension at the symptomatic level(s), while allowing flexion and unrestricted axial rotation and lateral bending.\textsuperscript{35} Biomechanical studies have shown that the implant significantly reduces intradiscal pressure and facet load and prevents narrowing of the spinal canal and neural foramina.\textsuperscript{36–38} The current study reports the 2-year outcomes from a prospective, randomized, multicenter study of NIC patients. The specific aims of the study were to measure the percentage of improvement of patients treated nonoperatively and with the X STOP. The authors hypothesized that the X STOP would be significantly more effective than conservative care at all follow-up visits.

### Patients and Methods

**Patient Selection.** One hundred ninety-one patients were enrolled in a prospective, randomized, controlled trial at 9 US centers over a 15-month period from May 2000 to July 2001. The study was conducted under a Food and Drug Administration-approved Investigational Device Exemption and was approved by the Institutional Review Board at each participating institution before initiation. All patients signed an Institutional Review Board-approved informed consent form before participation in the study. Patient eligibility to participate in the study was based on the following key inclusion and exclusion criteria.

**Key Inclusion Criteria.** Patients had to be at least 50 years old and have leg, buttock, or groin pain with or without back pain that was relieved during flexion. To identify a study population of patients with more moderate symptoms of NIC, patients had to be able to walk at least 50 feet.

**Key Exclusion Criteria.** Patients could not have a fixed motor deficit, cauda-equina syndrome, previous lumbar surgery of the stenotic level, or spondylolisthesis greater than grade I on a scale of I to IV at the affected level(s).

**Randomization.** Block randomization by site was used to ensure a balanced proportion of X STOP and control subjects in each clinical site and for the entire study. The date of surgery was considered as the treatment date for X STOP patients, and the date of the initial epidural injection was considered as the treatment date for control patients.

**Control Group.** Nonoperative therapy was selected as a control in the current study, both because it is the standard of care in the treatment for patients with mild to moderate NIC and because implantation of the X STOP, like nonoperative care, does not require the patient to undergo a highly invasive procedure. Patients randomized to the control group received at least one epidural steroid injection following enrollment and were prescribed additional epidural steroid injections, nonsteroidal anti-inflammatory medications, analgesics, and physical therapy as necessary. Physical therapy consisted of back school and methods such as ice packs, heat packs, massage, stabilization exercises, and pool therapy.

**X STOP Group.** Patients randomized to the X STOP group underwent surgery for implantation of the device, which consists of two components: a spacer assembly and a wing assembly. The X STOP is placed between the spinous processes from a lateral direction without resecting the supraspinous ligament or the removing of any tissue (Figure 1). The surgical technique is described in more detail by Zucherman et al.\textsuperscript{34}

**Outcomes Assessment.** Assessments were made before treatment (baseline) and at 6 weeks, 6 months, 1 year, and 2 years following treatment. Assessment of the primary outcome was based on data collected using the patient-completed Zurich Claudication Questionnaire (ZCQ), which consists of Symptom Severity and Physical Function domains that are completed before and after surgery and the Patient Satisfaction domain that is completed after surgery.\textsuperscript{39,40} The mean percent improvement from baseline in the Symptom Severity and Physical Function domains was calculated for each patient at each time point. Also, the proportion of patients in both groups who were clinically significantly improved and who were satisfied with their treatment was compared at each follow-up time point. The mean percent improvement from baseline in the Symptom Severity and Physical Function domains was compared between the X STOP and control groups using an ANOVA with a level of significance of 0.05. The percentage of patients who had significant clinical improvement in each domain was compared between the X STOP and control groups using the Fisher exact test with a level of significance of 0.05. Pretreatment variables including baseline scores, patient demographics such as age or gender, the presence of comorbid conditions, and operative variables for X STOP patients were correlated with treatment success using univariate and multivariate regression analyses to determine predictors of outcomes. All independent variables associated with levels of sig-
surgery until patients completed the study. Greater than 24 hours.

were in the hospital less than 24 hours and four stayed performed under local anesthesia in 97 patients and un-

age blood loss was 46 mL. The most common level im-

Spondylolisthesis present 35/100 24/90 0.272

Baseline PF 2.48 (0.48) 2.48 (0.51) 0.938

Baseline SS 3.14 (0.56) 3.10 (0.51) 0.582

Weight (kg) 80.4 (15.8) 81.8 (18.9) 0.569

Age (years) 70.0 (9.8) 69.1 (9.9) 0.513

Note. mean (SD).

* Student’s t test.

Radiographic Analysis. All patients underwent a radiographic examination at each follow-up visit. The examination included anteroposterior and sagittal plain radiographs of the lumbar spine in the neutral or standing position. The distance between the spinous processes of the implanted levels of X STOP was compared between the 6-week and 2-year radiographs using the method of Neumann et al. Additional measurements were made to determine if the X STOP resulted in any radiographic changes to the lumbar spine that could be of potential clinical significance, such as whether there was an increase or decrease in the angulation or curvature of the spine or whether there was an increase or decrease in the percentage of spondylolisthesis. Measurements in the X STOP patients were compared with measurements made in control patients at 1- and 2-year follow-up. All measurements were made by an independent radiologist and comparisons were performed using Student’s t test with a level of significance of 0.05.

Safety. Complications were assessed intraoperatively and after surgery until patients completed the study.

■ Results

Demographics and Baseline Variables

There were no significant differences in age, height, or weight between the two groups (Table 1). The mean age was 70 years in the X STOP group and 69.1 in the control group. Also, there were no significant differences in baseline Symptom Severity or Physical Function domain scores between the two groups (Table 1). Spondylolisthesis of Grade I or less was present in 35% of the X STOP patients and 27% of the control patients; the remaining patients had no spondylolisthesis present.

Operative Details

A total of 136 levels were implanted in 100 patients; 64 single levels and 36 double levels. The procedure took an average of 54 ± 18 minutes (mean ± SD), and the average blood loss was 46 mL. The most common level implanted was L4–L5 (89/136), and the second most common level was L3–L4 (43/136). The procedure was performed under local anesthesia in 97 patients and under general anesthesia in 3 patients. Ninety-six patients were in the hospital less than 24 hours and four stayed greater than 24 hours.

Table 1. Patient Demographics and Baseline Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>X STOP</th>
<th>Control</th>
<th>( P^* )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70.0 (9.8)</td>
<td>69.1 (9.9)</td>
<td>0.513</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>170.9 (9.7)</td>
<td>168.4 (11.2)</td>
<td>0.117</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>80.4 (15.8)</td>
<td>81.8 (18.9)</td>
<td>0.569</td>
</tr>
<tr>
<td>Baseline SS</td>
<td>3.14 (0.56)</td>
<td>3.10 (0.51)</td>
<td>0.582</td>
</tr>
<tr>
<td>Baseline PF</td>
<td>2.48 (0.48)</td>
<td>2.48 (0.51)</td>
<td>0.938</td>
</tr>
<tr>
<td>Spondylolisthesis present</td>
<td>35/100</td>
<td>24/90</td>
<td>0.272</td>
</tr>
</tbody>
</table>

Epidural Injections

All 91 patients in the control group received an epidural steroid injection following enrollment. An additional 125 injections were administered to control group patients over the course of the study, for a total of 216 injections. Fifty-nine control group patients received at least one additional injection after the initial injection at baseline: 22 patients received 1 additional injection, 21 patients received 2 additional injections, 8 patients received 3 additional injections, and 8 patients received 4 or more injections.

Patient Follow-up

At 2-years follow-up, data from 93 of the 100 X STOP patients and 81 of the 91 control patients were available for analysis. In the X STOP group, seven patients were lost to follow-up; four patients died, two patients failed to complete the ZCQ, and one patient withdrew. In the control group, ten patients were lost to follow-up; three patients died, one patient could not tolerate the initial epidural steroid injection which was aborted, and six patients withdrew. Outcomes from these patients are not included in the results. None of the deaths in the study were attributable to treatment in either group.

Primary Outcomes

The mean percent improvement of the Symptom Severity and Physical Function domain scores in the X STOP group were significantly greater than those of the control group at each time point (Figures 2 and 3). At 2 years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X STOP group and by 7.4% in the control group \( (P < 0.001) \). There were no significant differences between time points for either the X STOP \( (P > 0.590) \) or control groups \( (P > 0.900) \). The percent change for each patient at each time point was calculated as the change from baseline relative to the baseline score, i.e., \( \text{(Baseline score – score)} / \text{Baseline score} \).

Figure 2. The mean percent change of the Symptom Severity scores relative to each patient’s baseline score. At each time point, the mean percent change of the X STOP patient’s score was significantly greater than that of the control patient’s score \( (P < 0.001) \). There were no significant differences between time points for either the X STOP \( (P > 0.590) \) or control groups \( (P > 0.900) \). The percent change for each patient at each time point was calculated as the change from baseline relative to the baseline score, i.e., \( \text{(Baseline score – score)} / \text{Baseline score} \).
At each time point, the mean percent change of the X STOP patient's score was significantly greater than that of the control patient's score ($P < 0.001$). There were no significant differences between time points for either the X STOP ($P > 0.087$) or control groups ($P > 0.270$). The percent change for each patient at each time point was calculated as the change from baseline relative to the baseline score, i.e., \[
\frac{\text{Baseline score} - \text{score}_{i}}{\text{Baseline score}}.
\]

### Predictors of Outcomes

In the univariate analysis, 13 variables were significantly correlated to patient success in the X STOP group, and three of these variables remained significant in the multivariate model (Table 2). A positive femoral stretch test, the absence of comorbid conditions, and lower surgical blood loss were the most significant predictors of patient success in the univariate analysis and the only significant predictors in the multivariate analysis. No variables associated with the control group were significant in the univariate analysis and the only significant predictors of patient success in the univariate analysis and the only significant predictors in the multivariate model (Table 2). A positive femoral stretch test, the absence of comorbid conditions, and lower surgical blood loss were the most significant predictors of patient success in the univariate analysis and the only significant predictors in the multivariate analysis. No variables associated with the control group were significant in the univariate analysis and the only significant predictors in the multivariate analysis.

The presence of spondylolisthesis was not predictive of outcomes although 55.9% (19 of 34) of the X STOP patients with spondylolisthesis were clinically successful compared with 44.1% (26 of 59) of patients without spondylolisthesis.

### Additional Surgery

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. Postlaminectomy outcomes are available for 28 patients (6 X STOP and 22 control patients). The mean follow-up time for this group was 12.8 months (range 2.5–26.9 months). The patients undergoing a laminectomy improved by 33.2% in the Symptom Severity domain and by 37.9% in the Physical Function domain. Sixteen of 28 (57.1%) patients had significant clinical improvement in Symptom Severity, and 15 of 28 (53.6%) satisfied with the outcome of their treatment (Table 3). Forty-three percent (12/28) of laminectomy patients met all three of the ZCQ criteria.

### Safety/Complications

No device-related intraoperative complications occurred, and investigators were able to complete implantation of the X STOP in all patients. No procedures were converted to a laminectomy at the time of X STOP surgery.

Three complications occurred intraoperatively or within 72 hours following surgery in the X STOP group (Table 4). There was one episode of respiratory distress and one ischemic coronary episode that resolved without clinical sequelae. One X STOP patient with a history of

### Table 2. Predictors of Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariate</th>
<th>Multi-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimate</td>
<td>$P$</td>
</tr>
<tr>
<td>Femoral stretch test</td>
<td>-1.70</td>
<td>0.001 *</td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td>1.39</td>
<td>0.003 *</td>
</tr>
<tr>
<td>Blood loss</td>
<td>0.02</td>
<td>0.004 *</td>
</tr>
<tr>
<td>ZCQ physical function</td>
<td>-1.40</td>
<td>0.005 *</td>
</tr>
<tr>
<td>SF-36 social functioning</td>
<td>0.02</td>
<td>0.010 *</td>
</tr>
<tr>
<td>Range of motion-extension</td>
<td>-0.06</td>
<td>0.012 *</td>
</tr>
<tr>
<td>SF-36 bodily pain</td>
<td>0.04</td>
<td>0.013 *</td>
</tr>
<tr>
<td>Range of motion-rotation</td>
<td>-0.04</td>
<td>0.021 *</td>
</tr>
<tr>
<td>Employed</td>
<td>-0.98</td>
<td>0.004 *</td>
</tr>
<tr>
<td>Age</td>
<td>0.04</td>
<td>0.048 *</td>
</tr>
<tr>
<td>L4-L5 involvement</td>
<td>-2.06</td>
<td>0.058 *</td>
</tr>
<tr>
<td>Back pain present</td>
<td>1.14</td>
<td>0.075 *</td>
</tr>
<tr>
<td>Use of narcotics</td>
<td>-0.75</td>
<td>0.081 *</td>
</tr>
</tbody>
</table>

NS = not significant.  
* Indicates a level of significance $< 0.1$.  
† Indicates a level of significance $< 0.05$.

### Table 3. Comparison of X STOP and Laminectomy ZCQ Outcomes

<table>
<thead>
<tr>
<th></th>
<th>X STOP</th>
<th>Laminectomy</th>
<th>$P^*$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom severity</td>
<td>56/93</td>
<td>16/28</td>
<td>0.827</td>
</tr>
<tr>
<td>Physical function</td>
<td>53/93</td>
<td>18/28</td>
<td>0.520</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>68/93</td>
<td>15/28</td>
<td>0.064</td>
</tr>
<tr>
<td>Overall success</td>
<td>45/93</td>
<td>12/28</td>
<td>0.669</td>
</tr>
</tbody>
</table>

* Fisher's exact test.
cardiovascular disease developed pulmonary edema 2 days following device implantation. This patient subsequently died. There were four minor operative site-related complications in the immediate postoperative period: one wound dehiscence, one swollen wound that was aspirated, one hematoma, and one report of incisional pain (Table 4). There were three device-related complications in the X STOP group (Table 4). One X STOP patient suffered a fall that caused the implant to dislodge. The dislodged implant was removed without sequelae. An asymptomatic spinous process fracture was diagnosed in another patient on routine 6-month follow-up radiographs, which required no further medical treatment or surgical intervention. One patient reported worsening pain 382 days following treatment, which was determined to be possibly related to the implant. Finally, one implant was placed posterior enough to be considered malpositioned.

Five complications were associated with the epidural injection (Table 4). One patient was unable to tolerate the injection, and the investigator abandoned the procedure; one patient had a severe flare in symptoms and was admitted overnight; two patients had leg paresthesias and were discharged following observation; and one patient sought treatment at an emergency room for back pain 6 hours following the injection. Another patient suffered a heart attack 3 days following treatment; it is unknown whether the heart attack was related to the injection procedure.

Distraction was maintained in 96% of the levels implanted with the X STOP, defined as no measurable change in the distance between the spinous processes when radiographs taken at the 6 week follow-up were compared with radiographs taken at the 2-year follow-up. There were no significant differences between the X STOP and control groups in the mean values of any other radiographic measurements made at either the 1-year or 2-year follow-up visits (Table 5).

Table 4. Complications of X STOP and Control Patients

<table>
<thead>
<tr>
<th>Complication</th>
<th>X STOP (N = 100)</th>
<th>Control (N = 91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative or procedure related</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>1 1.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Coronary episode, ischemic</td>
<td>1 1.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>1 1.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Wound swelling</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Incisional pain</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Injection intolerance</td>
<td>NA NA</td>
<td>1 1.1%</td>
</tr>
<tr>
<td>Symptom flare</td>
<td>NA NA</td>
<td>1 1.1%</td>
</tr>
<tr>
<td>Leg paresthesia</td>
<td>NA NA</td>
<td>2 2.2%</td>
</tr>
<tr>
<td>Increased back pain</td>
<td>NA NA</td>
<td>1 1.1%</td>
</tr>
<tr>
<td>Heart attack</td>
<td>NA NA</td>
<td>1 1.1%</td>
</tr>
<tr>
<td>Device related</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malpositioned implant</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Implant dislodgement/migration</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Spinous process fracture</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
<tr>
<td>Increased pain at implant level</td>
<td>1 1.0%</td>
<td>NA NA</td>
</tr>
</tbody>
</table>

NA = not applicable.

Table 5. Mean Radiographic Measurements, 12- and 24-Month Follow-up Visits

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Follow-up (months)</th>
<th>X STOP</th>
<th>Control</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinous process Distance (mm)</td>
<td>12</td>
<td>52.1 (7.1)</td>
<td>51.0 (7.0)</td>
<td>0.336</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>51.8 (7.4)</td>
<td>51.2 (7.1)</td>
<td>0.592</td>
</tr>
<tr>
<td>Anterior disc height (mm)</td>
<td>12</td>
<td>9.9 (4.2)</td>
<td>9.7 (3.8)</td>
<td>0.776</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>9.0 (4.1)</td>
<td>8.9 (4.3)</td>
<td>0.839</td>
</tr>
<tr>
<td>Posterior disc height (mm)</td>
<td>12</td>
<td>5.3 (2.5)</td>
<td>5.1 (2.3)</td>
<td>0.626</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>4.6 (2.3)</td>
<td>4.6 (2.2)</td>
<td>0.935</td>
</tr>
<tr>
<td>Treated level angulation (deg)</td>
<td>12</td>
<td>14.6 (7.4)</td>
<td>16.5 (6.7)</td>
<td>0.099</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>15.1 (7.1)</td>
<td>15.5 (7.6)</td>
<td>0.707</td>
</tr>
<tr>
<td>L1–L5 angulation (deg)</td>
<td>12</td>
<td>34.4 (11.9)</td>
<td>33.5 (14.1)</td>
<td>0.701</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>35.6 (11.5)</td>
<td>32.8 (13.1)</td>
<td>0.198</td>
</tr>
<tr>
<td>Foraminal height (mm)</td>
<td>12</td>
<td>23.2 (2.5)</td>
<td>22.5 (2.5)</td>
<td>0.088</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>21.2 (2.8)</td>
<td>21.5 (2.7)</td>
<td>0.412</td>
</tr>
<tr>
<td>Spondylolisthesis (%)</td>
<td>12</td>
<td>4.1 (8.7)</td>
<td>5.9 (9.0)</td>
<td>0.201</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>4.7 (9.2)</td>
<td>7.0 (10.4)</td>
<td>0.154</td>
</tr>
<tr>
<td>L1–L5 coronal curve (deg)</td>
<td>12</td>
<td>4.9 (4.2)</td>
<td>5.8 (5.5)</td>
<td>0.267</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>6.1 (5.5)</td>
<td>4.9 (4.1)</td>
<td>0.193</td>
</tr>
</tbody>
</table>

Note. Mean (SD).

* Student’s t test.
patient satisfaction following treatment for NIC. The results of this study and the previous report by Zucher-
man et al34 demonstrate that the X STOP significantly improves symptoms and function compared with ep-
idural steroid injections and conservative therapy at 6-week, 6-month, 1-year, and 2-year follow-up.

The presence of comorbid conditions was a negative predictor of outcomes in this trial, which has been noted in outcomes of decompressive surgery for LSS. Katz et al31 reported that patients with greater co-morbidities and worse self-rated health, physical function, symptom severity, and depression were associated with worse outcomes. Jonsson et al30 reported that 23 of the 50 patients had concomitant diseases that affected walking ability and likely the outcomes.

To place the outcomes of the X STOP in the spectrum of current treatment alternatives for NIC, we have com-
pared the outcomes of the relevant literature regarding the safety and efficacy of decompressive laminectomy 
with the X STOP outcomes.26,31,32,43–45 In a study by Johnsson et al,35 approximately 60% of the LSS patients 
treated surgically graded their condition as improved, whereas approximately 40% were either unchanged or worse. In a study by Amundsen et al,26 15 of 48 (31%) of patients treated surgically assessed their pain as none to 
light and could be considered clinically successful. In two successive reports by Atlas et al,32,46 between 60 and 
70% of the surgical patients were satisfied following sur-
ery, and their predominant symptom was “better” in 
approximately 55 to 70% of the patients. Using a more 
rigorous definition of clinical success, Gunzburg et al44 
reported that 21 of 36 (58%) reported improvement in 
two of the four outcomes measures (visual analog pain 
intensity score, Oswestry Low Back Pain Disability Ques-
tionnaire, Waddell Disability Index, and Low Back Out-
come Score), used in their study, and 14 of 36 (39%) 
reported improvement in all four outcomes measures. 
Katz et al reported outcomes in 197 patients with 2 year 
follow-up, using the ZCQ and the same success crite-
ria in a patient population similar to those enrolled in 
this study. Katz et al31,43 reported that 63% of the 
patients were significantly improved in Symptom Se-
verity, 59% were improved in Physical Function, and 
72% were satisfied (Figure 4). Forty-seven percent of 
patients met all three criteria. These results confirm that 
outcomes of X STOP patients are comparable with the 
results of patients undergoing decompressive laminecto-
y.26,31,32,43–45 There were also no significant differ-
ences in the outcomes of the 6 X STOP and 22 control 
patients who underwent a decompressive laminectomy 
compared with the X STOP using the same outcomes 
measure (Figure 4).

Although the outcomes of the X STOP and surgical 
decompression procedures are comparable, there are sig-
nificant differences in the risks associated with the two 
surgical procedures. Mean operative time for the X 
STOP procedure was 54 minutes, which is considerably 
less than the range of 72 to 278 minutes reported for 
the X STOP procedure was 54 minutes, which is considerably 
less than the range of 72 to 278 minutes reported for

<table>
<thead>
<tr>
<th>Symptom Severity</th>
<th>Physical Function</th>
<th>Patient Satisfaction</th>
<th>All Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>20%</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td>40%</td>
<td>60%</td>
<td>80%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Figure 4. A comparison of outcomes for NIC patients treated with 
de compressive laminectomy and the X STOP.

laminectomy procedures.11,30,47–50 Also, the mean blood 
loss of 46 mL during the X STOP procedure is consid-
erably less than the range of 115 to 1040 mL reported 
for decompressive surgery.11,30,47,48,50 Complications 
reported for laminectomy include paralysis, myocardial 
infarction, pulmonary embolism, pneumonia, he-
matoma, deep vein thrombosis, neurologic deficit, 
deep infection, superficial infection, dural tears, implant 
failure (when accompanied by a fusion), and pseudar-
throsis.7,32,33,47,51–53 Turner’s meta-analysis reported the 
following complication rates for NIC surgery: peri-
operative mortality (0.32%), dural tears (5.91%), deep 
infection (1.08%), superficial infection (2.3%), deep 
vein thrombosis (2.78%), any complication (12.64%).53 
None of these major complications was reported as a 
result of the X STOP procedure. Because the X STOP is 
not implanted adjacent to nerve roots or the spinal cord, 
the risk of neurologic deficit or paralysis may be consid-
ered minimal, and no incidence of either complication 
was reported in this study. Compared with the incidence 
and severity of complications cited in the laminectomy 
literature, the complications associated with the X STOP 
procedure suggest that the procedure is at least as safe as 
a decompressive laminectomy, and likely safer. In addi-
tion, the X STOP does not result in any significant radi-
ographic changes to the lumbar spine. There were no dif-
f erences between the mean disc height, curvature of the 
spine, or angulation of the spine of X STOP and control 
patients compared at 1 and 2 years. There was also no 
difference in the degree of spondylolisthesis between the 
X STOP and the control groups.

The incidence of a second operation for unresolved 
stenosis symptoms in the X STOP group was 6% 
through 2-year follow-up, a rate of reoperation favor-
able comparable with rates reported in the clinical liter-
ature for the surgical treatment of stenosis.29,30,32,54 At-
las et al reported a 6% reoperation rate at 1 year 
follow-up for 81 patients. Markwalder et al reported a 
reoperation rate of 12% (12 of 100 patients) at a mean 
follow-up period of 2.9 years, and Jonsson et al reported a reoperation rate of 18% (19 of 105 patients) 
occuring from 0.5 years to 4.5 years after the initial 
operation. Katz et al reported a reoperation rate of 6%
at 1 year follow-up (5 of 88), which increased to 17% at a median follow-up period of 4.2 years.

Outcomes in the control group were significantly worse than those reported in the clinical literature for nonoperative therapy. However, the low success rate for nonoperative therapy should be considered a result of the rigorous outcomes measure used in the study, and not a confirmation that nonoperative therapy is not efficacious. NIC patients are typically considered as successes in the clinical literature if they experience at least some improvement after undergoing nonoperative therapy. Hurri et al. reported that 44% had at least some improvement in neurologic symptoms, and Atlas et al. found that 32% of the patients treated nonoperatively considered their condition improved. In this trial, 44% of control patients experienced at least some improvement in pain symptoms and 43% experienced some improvement in their physical function. The outcomes of the control group in this study were consistent with and comparable with results reported in the literature.

The genesis of the concept that an implant placed between the spinous processes might provide relief for patients suffering from neurogenic intermittent claudication came about from a straightforward clinical observation; most of these patients get relief of symptoms when they bend forward and flex their spines and conversely their symptoms worsen when they stand erect and extend their spines. Results of this randomized, multicenter trial clearly demonstrate that the X STOP improves clinical symptoms and function significantly compared with epidural steroid injections and conservative therapy in patients with symptoms of NIC. In each domain of the primary outcomes measure, X STOP patients had significantly better outcomes at every follow-up visit. The absence of any major complications demonstrates that the X STOP is safe. Because the X STOP procedure may be performed with a small exposure under local anesthesia, this treatment represents an attractive alternative for NIC patients.

The X STOP provides a conservative, yet effective, treatment for patients suffering from lumbar spinal stenosis. In the continuum of treatment options, the X STOP offers an attractive alternative to both nonoperative treatment and decompression surgery for patients with symptoms related to lumbar spinal stenosis.

● Using a validated, patient-completed, condition-specific outcomes measure, the efficacy of the X STOP treatment was significantly greater than the control group, yet with a comparably low complication rate.

● The X STOP is a safe and effective treatment for neurogenic intermittent claudication patients compared with both nonoperative therapy and decompressive surgery.

Key Points

- A randomized, controlled, prospective multicenter trial of neurogenic intermittent claudication patients was conducted to compare the safety and efficacy of the X STOP interspinous implant with nonoperative therapy.

References


