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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-

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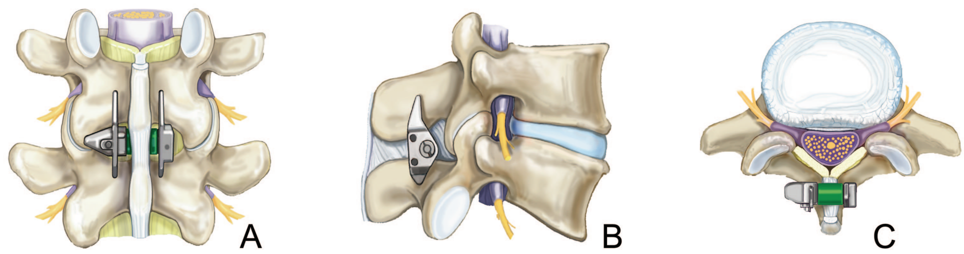

Figure 1. A schematic of the X STOP *in situ*. The posterior (**A**), lateral (**B**), and axial (**C**) views show that the implant is placed between the spinous process. The lateral wings prevent anterior and lateral migration, and the supraspinous ligament prevents posterior migration.

ported in the clinical literature is quite variable, and the procedure is associated with a relatively high complication and reoperation rate.[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%.[33]

The interspinous process decompression system (X STOP) provides an alternative therapy to conservative treatment and decompressive surgery for patients suffering from NIC.[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.[35] Biomechanical studies have shown that the implant significantly reduces intradiscal pressure and facet load and prevents narrowing of the spinal canal and neural foramens.[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*[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.[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-

Table 1. Patient Demographics and Baseline Variables

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

Note. mean (SD).
* Student's *t* test.

nificance <0.1 in the univariate analyses were included in multiple logistic regression models with stepwise selection of variables.

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.*[41] 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.

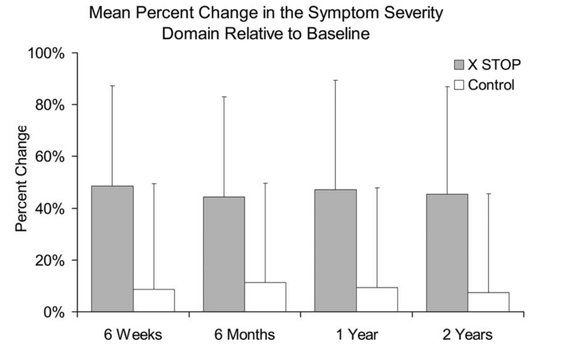

Figure 2. The mean percent change of the Symptom Severity scores relative to each patient's baseline score. At each time point, the mean percent change of the X STOP patient's score was significantly greater than that of the control patient's score ($P < 0.001$). There were no significant differences 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.*, (Baseline score − $score_t$)/Baseline score.

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 ($P < 0.001$). At the same time point, the mean Physical Function scores improved by 44.3% in the X STOP group and by −0.4% in the control group ($P < 0.001$). These findings were consistent for the two domains at all time points (Figures 2 and 3). In the X STOP group, there were no significant differences between the mean percent improvement at any two fol-

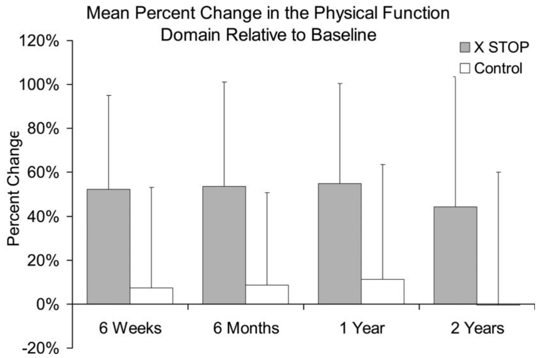

Figure 3. The mean percentage change of the Physical Function scores relative to each patient's baseline score. At each time point, the mean percent change of the X STOP patient's score was significantly greater than that of the control patient's score ($P < 0.001$). There were no significant differences between time points for either the X STOP ($P > 0.087$) 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.*, (Baseline score $-$ $score_t$)/Baseline score.

low-up time points in the Symptom Severity or Physical Function domains ($P > 0.59$ and $P > 0.087$, respectively). In the control group, there were no significant differences between the mean percent improvement at any two follow-up time points in the Symptom Severity or Physical Function domains ($P > 0.9$ and $P > 0.27$, respectively).

At the 2-year evaluation, 56 of 93 patients (60.2%) reported a clinically significant improvement in the Symptom Severity domain compared with 15 of 81 patients (18.5%) in the control group ($P < 0.001$), 53 of 93 patients (57.0%) reported clinically significant improvement in the Physical Function compared with 12 of 81 patients (14.8%) in the control group ($P < 0.001$), and 68 of 93 patients (73.1%) were at least somewhat satisfied compared with 28 of 78 patients (35.9%) in the control group ($P < 0.001$). The proportion of patients who satisfied all three ZCQ criteria was 48.4% in the X STOP group compared with 4.9% in the control group. The percentage of patients with significant clinical improvement at 6 weeks, 6 months, and 1 year has been reported previously.[34]

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. 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.

Table 2. Predictors of Outcomes

X STOP Group	Univariate		Multi- Factor	
Variable	Estimate	*P*	Estimate	*P*
Femoral stretch test	−1.70	0.001 *	−1.50	0.010 †
Comorbid conditions	1.39	0.003 *	1.33	0.013 †
Blood loss	0.02	0.004 *	0.02	0.007 †
ZCQ physical function	−1.40	0.005 *		NS
SF-36 social functioning	0.02	0.010 *		NS
Range of motion-extension	−0.06	0.012 *		NS
SF-36 bodily pain	0.04	0.013 *		NS
Range of motion-rotation	−0.04	0.021 *		NS
Employed	−0.98	0.034 *		NS
Age	0.04	0.048 *		NS
L4–L5 involvement	−2.06	0.058 *		NS
Back pain present	1.14	0.075 *		NS
Use of narcotics	−0.75	0.081 *		NS

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

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, 18 of 28 (64.3%) had significant clinical improvement in Physical Function, and 15 of 28 (53.6%) were 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 3. Comparison of X STOP and Laminectomy ZCQ Outcomes

	X STOP	Laminectomy	*P**
Symptom severity	56/93 (60.2%)	16/28 (57.1%)	0.827
Physical function	53/93 (57.0%)	18/28 (64.3%)	0.520
Patient satisfaction	68/93 (73.1%)	15/28 (53.6%)	0.064
Overall success	45/93 (48.4%)	12/28 (42.9%)	0.669

* Fisher's exact test.

Table 4. Complications of X STOP and Control Patients

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

NA = not applicable.

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).

■ Discussion

Currently available options to treat NIC are limited to either nonoperative therapy or decompressive lumbar laminectomy, with or without a fusion. With the exception of the 1-year report by Zucherman *et al*,[34] no randomized, prospective, multicenter study has been performed on NIC patients to determine the efficacy of either nonoperative therapy or surgical decompression.[33,42] Few studies are prospective, the follow-up data collection methods are unclear, rarely is the data analyzed by someone other than the treating physician, and the outcomes are not assessed at consistent time intervals.[33,42]

The current study reports the 2-year outcomes of NIC patients in a randomized, prospective, multicenter study using a validated, patient-completed instrument to quantify a change in the symptoms, physical function, and

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

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

Note. Mean (SD).
* Student's *t* test.

patient satisfaction following treatment for NIC. The results of this study and the previous report by Zucherman *et al*[34] demonstrate that the X STOP significantly improves symptoms and function compared with epidural 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 al*[31] 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 al*[30] 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 compared 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*,[45] 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 surgery, and their predominant symptom was "better" in approximately 55 to 70% of the patients. Using a more rigorous definition of clinical success, Gunzburg *et al*[44] reported that 21 of 36 (58%) reported improvement in three of the four outcomes measures (visual analog pain intensity scale, Oswestry Low Back Pain Disability Questionnaire, Waddell Disability Index, and Low Back Outcome 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 criteria in a patient population similar to those enrolled in this study. Katz *et al*[31,43] reported that 63% of the patients were significantly improved in Symptom Severity, 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 laminectomy.[26,31,32,43–45] There were also no significant differences 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 significant 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 laminectomy procedures.[11,30,47–50] Also, the mean blood loss of 46 mL during the X STOP procedure is considerably 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, hematoma, deep vein thrombosis, neurologic deficit, deep infection, superficial infection, dural tears, implant failure (when accompanied by a fusion), and pseudarthrosis.[7,32,33,47,51–53] Turner's meta-analysis reported the following complication rates for NIC surgery: perioperative mortality (0.32%), dural tears (5.91%), deep infection (1.08%), superficial infection (2.3%), deep vein thrombosis (2.78%), any complication (12.64%).[33] 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 considered 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 addition, the X STOP does not result in any significant radiographic changes to the lumbar spine. There were no differences 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.

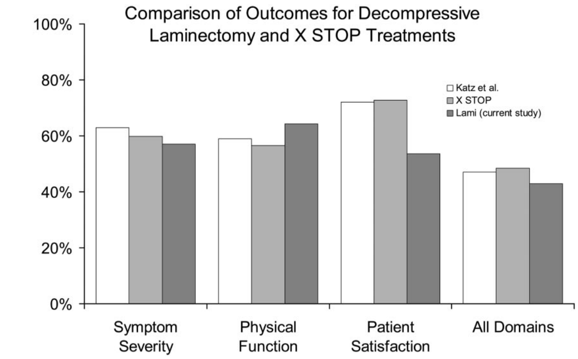

Figure 4. A comparison of outcomes for NIC patients treated with decompressive laminectomy and the X STOP.

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 favorably comparable with rates reported in the clinical literature for the surgical treatment of stenosis.[29,30,32,54] Atlas *et al*[32] reported a 6% reoperation rate at 1 year follow-up for 81 patients. Markwalder *et al*[29] reported a reoperation rate of 12% (12 of 100 patients) at a mean follow-up period of 2.9 years, and Jonsson *et al* [30] reported a reoperation rate of 18% (19 of 105 patients) occurring from 0.5 years to 4.5 years after the initial operation. Katz *et al*[54] 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.[10,26,32,45,46,55] Hurri *et al*[10] reported that 44% had at least some improvement in neurologic symptoms, and Atlas *et al*[32] reported 45% had improvement in leg pain. Johnsson *et al*[45] 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.

■ 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.
- 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.

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