

Clinical Study

# Scoliosis and interspinous decompression with the X-STOP: prospective minimum 1-year outcomes in lumbar spinal stenosis

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## Abstract

**BACKGROUND CONTEXT:** The X-STOP interspinous decompression device, as a treatment for neurogenic intermittent claudication (NIC) because of lumbar spinal stenosis (LSS), has been shown to be superior to nonoperative control treatment. Current Food and Drug Administration labeling limits X-STOP use to NIC patients with a maximum of 25° concomitant lumbar scoliosis. This value was arrived at arbitrarily by the device developers and is untested.

**PURPOSE:** To determine X-STOP utility for NIC in patients with concomitant lumbar scoliosis.

**STUDY DESIGN:** A prospective, single institution, clinical outcome study comparing patients with scoliosis with patients without scoliosis who underwent X-STOP interspinous decompression for NIC because of LSS.

**PATIENT SAMPLE:** A cohort of 179 consecutive patients, 63 with scoliosis (Cobb angle 11° or more) and 116 without scoliosis, with symptoms attributable to NIC treated between January 2006 and May 2007, were included in the study.

**OUTCOME MEASURES:** All patients completed self-reported preoperative and minimum 1-year postoperative outcome forms. Functional measures included Oswestry Disability Index (ODI), visual analog scale (VAS) pain score, and maximum walking and standing times in minutes. Three questions measured patient satisfaction: How satisfied were you with the procedure (very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied); Would you have the procedure again? (yes or no); Would you recommend the procedure to a friend? (yes or no).

**METHODS:** Before analysis, the 179 consecutive X-STOP patients were divided into three groups: Group 1 (controls without scoliosis, n=116); Group 2 (low scoliosis: 11–25°, n=41), and Group 3 (high scoliosis: 26° or more, n=22). The three groups were not statistically different for any preoperative functional scores. Groups were analyzed for pre- to postoperative functional change and level of satisfaction. Segmental scoliosis at the treated level was also analyzed.

**RESULTS:** Fifty-six percent of Group 1 and Group 2 patients, but only 18% of Group 3 patients, achieved the success criterion of an ODI improvement of 15 or more points (Group 3 the outlier, p=.004). The satisfaction rate was Group 1, 76%; Group 2, 78%; Group 3, 59% (Group 3 the outlier, p=.0001). On average, all three groups improved for each outcome: Group 1 (ODI 17.3, VAS 2.0, standing time 39 minutes, and walking time 43 minutes), Group 2 (ODI 20.0, VAS 1.9, standing time 65 minutes, and walking time 64 minutes), Group 3 (ODI 7.2, VAS 0.9, standing time 18 minutes, and walking time 16 minutes). There was no statistical relationship between any outcome and segmental scoliosis.

FDA device/drug status: not applicable.

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**CONCLUSIONS:** The outcome success rate for the X-STOP procedure to treat NIC is lower in patients with overall lumbar scoliosis more than 25° but is unaltered by segmental scoliosis at the affected level. Although patients and surgeons must be aware that the presence of more than 25° of scoliosis portends less favorable results with X-STOP implantation for NIC because of LSS, success in these patients is not precluded, and selection of treatment must be put into the context of individual patient risk and other treatment options. © 2010 Elsevier Inc. All rights reserved.

*Keywords:* Scoliosis; X-STOP; Interspinous decompression; Neurogenic intermittent claudication; Lumbar spinal stenosis

## Introduction

The X-STOP is an interspinous process decompression device for the treatment of neurogenic intermittent claudication (NIC) because of lumbar spinal stenosis (LSS). The X-STOP device and procedure are safe and effective with a satisfaction rate of approximately 73% in operated patients compared with 36% for nonoperatively treated controls [1].

That the X-STOP is superior to nonoperative control treatment was established during the initial Food and Drug Administration (FDA) approval trial, and that the outcomes may be durable to at least 4 years have been subsequently shown [1,2]. In the presence of concomitant degenerative scoliosis, however, the relationship of X-STOP treatment for NIC to patient outcome has not been evaluated. Current FDA labeling restricts X-STOP use to those NIC patients with overall scoliosis up to 25°. This cutoff was arrived at arbitrarily by the device developers for use in the initial FDA approval trial and remains untested.

We report the outcome differences among 63 scoliotic patients treated for clinically apparent NIC using the X-STOP compared with 116 X-STOP controls treated similarly, but without scoliosis. Minimum 1-year follow-up results are presented.

## Materials and methods

### *Patient selection*

One hundred seventy-nine consecutive patients that underwent X-STOP implantation between January 2006 and May 2007 at a single institution with minimum 1-year outcome data were included in the study. Of the 63 patients with scoliosis (11° Cobb angle or greater), it was decided preanalysis to subdivide them into two groups, low and high. The cutoff selected was 25° in accordance with current FDA labeling. This created a group of 41 scoliotic patients with a curve magnitude from 11° to 25° and 22 scoliotic patients with curve magnitude greater than 25°. One hundred sixteen patients without scoliosis (coronal deformity 10° or less) served as controls to compare relative differences in outcomes among the groups. Informed consent was obtained from all patients before inclusion, and the study was approved by the institutional review board.

### *Key inclusion criteria*

Patients, scoliotic or not, had to carry a clinical diagnosis of lumbar spinal stenosis with leg, buttock, or groin pain (with or without back pain) consistent with NIC. In particular, they had to experience relief with sitting or flexion of the lumbar spine.

### *Key exclusion criteria*

Patients were excluded for cauda equina syndrome, active infection, fixed lower extremity motor deficit, previous laminectomy at the stenotic level, greater than Meyerding Grade I (25%) degenerative spondylolisthesis, or any degree of isthmic spondylolisthesis. Scoliotic patients were excluded if symptoms were deemed attributable to scoliosis rather than NIC.

### *Radiographic measures*

Preoperative standing anteroposterior and lateral radiographs of the entire lumbar spine to include the lower thoracic spine and upper sacrum were taken for all patients. Levels above T9 were not routinely visualized. Overall maximal scoliosis was measured for the visualized portion of the spine using the Cobb angle. The segmental scoliosis for each spinal level instrumented with an X-STOP was measured using the inferior end plate of the vertebrae above and the superior end plate of the vertebra below.

### *Outcomes*

Patients completed self-reported preoperative and minimum 1-year postoperative outcome forms. The data included the Oswestry Disability Index (ODI), visual analog scale (VAS) for pain, and maximum sitting, standing, and walking time (in minutes). Three additional questions of patient satisfaction were assessed: How satisfied were you with the procedure? (very satisfied, somewhat satisfied, somewhat dissatisfied, very dissatisfied); Would you have the procedure again? (yes or no); Would you recommend the procedure to a friend? (yes or no).

### *Surgery*

All surgeries were performed at our institution by the X-STOP inventors or their fellowship-trained associates.

## EVIDENCE & METHODS

### Context

The X-Stop device is being used for the treatment of radicular or claudication symptoms secondary to lumbar spinal stenosis. The authors present their results in patients who also have lumbar scoliosis.

### Contribution

In this prospective observational study of consecutive patients having the procedure with coronal curves  $>11^\circ$ , the authors found that X-Stop provides less satisfactory results in patients with a greater than  $25^\circ$  overall scoliosis.

### Implication

Cohorts were not matched for baseline clinical characteristics given the consecutive enrollment design, and, therefore, the poorer outcomes seen with larger curves may not be only related to that observation. Other confounders may include degree of stenosis, areas of stenosis (canal versus foramen), medical or psychosocial comorbidities, etc. However, the observation that patients with  $>25^\circ$  of scoliosis appear to gain little functional recovery as measured by ODI and walking/standing times suggests that realism regarding potential outcomes, proper informed consent, and a careful balancing with risks are indicated prior to the use of X-Stop in this population.

—*The Editors*

The surgical technique has been previously described, and the reader is referred to those publications for a full description [2,3].

### Statistical analysis

Preoperative and 1-year postoperative outcome scores were assessed for change in each patient. All score differences for each outcome variable were adjusted so that positive values would reflect improvement, negative values worsening. The average change in each outcome variable was analyzed statistically against the two deterministic variables of segmental and overall scoliosis.

The outcome variables were analyzed according to the following. Oswestry Disability Index scores could range from 0 to 100, with 0 representing the absence of disability and 100 representing complete disability. An ODI improvement of 15 points or more was selected as a success criterion and is consistent with the FDA recommendations [2,4] and nearly a 95% certainty that a truly positive change has occurred in spinal stenosis patients [5]. An ODI worsening greater than six points was considered the minimally clinically important negative change, in agreement with studies

that have analyzed this parameter using patient-based anchors [6–8]. Visual analog scale scores could range from 0 to 10, with 0 representing the absence of pain and 10 representing the worst pain imaginable. It was treated as a continuous variable. Sitting, standing, and walking times were recorded in minutes and could range from 0 to indefinite (defined as 180 minutes or more and given a value of 180). All three were treated as continuous variables. The three patient satisfaction questions were treated as dichotomous categorical variables. The specific question related to surgical satisfaction was dichotomized into “satisfied” and “unsatisfied” by combining the somewhat satisfied and very satisfied groups as well as the somewhat dissatisfied and very dissatisfied groups.

The deterministic variables were overall scoliosis and segmental scoliosis. Overall scoliosis was defined as  $11^\circ$  or more of coronal plane spinal curvature. Three categorical groups of patients were defined before statistical analysis: Group 1 included all patients without scoliosis with 0 to  $10^\circ$  of coronal spinal curvature; Group 2 included all patients with scoliosis of  $11^\circ$  to  $25^\circ$ ; and Group 3 included all patients with scoliosis of  $26^\circ$  or more. The cutoffs were based on the classical definition of scoliosis ( $11^\circ$  Cobb angle or more) and the initial  $25^\circ$  limit used by the X-STOP inventors during preliminary testing. The segmental scoliosis for each instrumented level was recorded as a continuous variable. When two or more levels were instrumented, the level with the greatest segmental scoliosis was selected for analysis.

Statistical comparisons for the data were made using the Statistical Package for the Social Sciences (SPSS), version 13.0 (Chicago, IL, USA). Univariate analysis of variance testing was used to compare continuous outcome variables among the overall scoliosis groups and the Kruskal-Wallis test for categorical ones. When measurements of overall or segmental scoliosis were treated as continuous data, linear regression was used for comparison to the continuous outcome variables and logistic regression for the categorical ones. A p value of .05 was selected to represent significance. Multivariate analysis was also performed using logistic regression to determine which variables could predict whether an ODI change of at least 15 points might occur. The exact number of patients for each specific analysis varied slightly because patients occasionally filled out the questionnaires incompletely.

### Results

There were 179 patients total in the study, 116 in Group 1 ( $0\text{--}10^\circ$  overall coronal curvature), 41 in Group 2 ( $11\text{--}25^\circ$  of overall scoliosis), and 22 in Group 3 ( $26^\circ$  or more of overall scoliosis). The three groups did not differ statistically for preoperative measures of age, ODI, VAS, sitting, standing, or walking time. The maximum overall scoliosis in Group 3 was  $55^\circ$ . The most superior vertebra included to obtain the

Table 1  
Summary data

Variables	Group 1 (0–10°)	Group 2 (11–25°)	Group 3 (26° or more)
Average preoperative ODI	50	51	50
Average postoperative ODI	33	31	43
Average preoperative VAS	5.3	5.5	6.3
Average postoperative VAS	3.2	3.5	5.4
Average preoperative sitting time (min)	130	133	122
Average postoperative sitting time (min)	140	140	118
Average preoperative standing time (min)	20	16	10
Average postoperative standing time (min)	59	80	27
Average preoperative walking time (min)	17	11	8
Average postoperative walking time (min)	60	75	23
Average age (y)	72	73	77
Males:Females, (n)	59:57	18:23	7:15

ODI, Oswestry Disability Index; VAS, visual analog scale.

The three groups did not differ statistically for preoperative measures of age, ODI, VAS, sitting, standing, or walking time.

maximal scoliosis measurement for any patient was T11, the most inferior S1. Nearly all curves followed the pattern of an upper lumbar curve from T12 or L1 to L3 and a fractional compensatory curve from L3 to the sacrum below.

Preoperative and 1-year postoperative data for the three scoliosis groups are presented in Table 1. The average change, satisfaction, and success criteria for each outcome variable are presented in Table 2. Each group showed improvement after X-STOP in all outcome scores at 1 year compared with baseline with the exception of sitting time for Group 3.

Univariate analysis of overall scoliosis revealed a statistically significant difference among the groups for the change seen in all outcome variables at 1 year except VAS (Table 3). The difference occurred in Group 3 for all outcomes, with inferior improvement noted in this group. There was no statistical difference among the three groups for the percentage of patients with ODI worsening. Between Groups 1 and 2, there were no statistically significant differences for any of the outcome variables.

Segmental scoliosis at the treated level(s) was found in 53 patients and ranged from 1° to 19° in this cohort.

Forty-seven patients had 3° or more. Treated levels for the entire cohort included Level 3, L2–L5 (two patients); Level 2, L2–L4 (four patients), L3–L5 (64 patients), and L4–S1 (five patients); and Level 1, L2–L3 (two patients), L3–L4 (14 patients), L4–L5 (87 patients), and L5–S1 (one patient). No instance of multilevel X-STOP implantation across noncontiguous vertebral segments occurred. Segmental scoliosis, as a determinant, was not statistically associated with any of the outcomes.

Multivariate analysis using logistic regression confirmed statistical significance for overall scoliosis as a determinant for an ODI improvement of 15 or more points ( $p=.007$ ). Segmental scoliosis, gender, age, and presence of osteoporosis did not influence the regression model and were not statistically significantly associated with ODI improvement.

## Discussion

The data from this study suggest a threshold amount of overall, but not segmental, scoliosis decreases the likelihood for patient satisfaction and significant ODI improvement in persons undergoing X-STOP surgery for the

Table 2  
One-year outcome results for the three scoliosis groups

Variables	Group 1 (0–10°)	Group 2 (11–25°)	Group 3 (26° or more)
Average change in ODI (best, worst)	17.3 (77, –38)	20.0 (80, –10)	7.2 (54, –23)
Percentage of patients with minimum 15-point improvement in ODI	56	56	18
Percentage of patients with ODI worsening more than 6 points	12	5	9
Average change in VAS (best, worst)	2.0 (7, –5)	1.9 (8, –4)	0.9 (6, –3.5)
Average change in sitting time, min	10	7.4	–4.0
Average change in standing time (best, worst), min	39 (180, –30)	65 (180, –20)	18 (165, –29)
Average change in walking time (best, worst), min	45 (180, –30)	64 (179, –15)	16 (150, –19)
Percentage of patients satisfied with surgery	76	78	59
Percentage of patients who would do surgery again	78	78	55
Percentage of patients who would recommend surgery to a friend	83	92	64

ODI, Oswestry Disability Index; VAS, visual analog scale.

Positive values represent improvement except for the row-labeled percentage of patients with ODI worsening. Data extremes, which represent the best and worst change seen for individual patients in each group, are shown when applicable. Sitting time had little variability and was not expected to change as patients' symptoms did not generally occur in this position. The average decrement in sitting time in Group 3, a loss of 4 minutes from 122 minutes preoperatively to 118 minutes postoperatively, was statistically insignificant.

Table 3  
Univariate statistics

Variables	Comparison by overall scoliosis among Groups 1–3	p Value
Percentage of patients with minimum 15-point improvement in ODI	Group 1=Group 2>Group 3	.004
Percentage of patients with ODI worsening more than 6 points*	Group 1=Group 2=Group 3	.314
Average change in VAS	Group 1=Group 2=Group 3	.322
Average change in sitting time	Group 1=Group 2=Group 3	.767
Average change in standing time	Group 1=Group 2>Group 3	.04
Average change in walking time	Group 1=Group 2≥Group 3	.05
Percentage of patients satisfied with surgery	Group 1=Group 2>Group 3	.0001
Percentage of patients who would do surgery again	Group 1=Group 2>Group 3	.0001
Percentage of patients who would recommend surgery to a friend	Group 1=Group 2>Group 3	.0001

ODI, Oswestry Disability Index; VAS, visual analog scale.

Groups 1 and 2 showed greater improvement than Group 3 in all categories except VAS score and sitting time. Sitting time was not expected to change postoperatively as patients' symptoms were generally relieved in the sitting position before X-STOP implantation.

\* Note that Group 3 had no higher rate of worsening than Groups 1 and 2, rather a lesser degree of improvement.

treatment of NIC because of LSS. The results remain unchanged when controlling for patient age, gender, or presence of osteoporosis. The true threshold appears to occur between 23° and 28° of scoliosis from post hoc and multivariate analysis. In effect, patients are less likely to be satisfied or realize a 15-point improvement in ODI when attempting to treat symptoms of NIC because of lumbar spinal stenosis with the X-STOP if their spine has more than approximately 25° of coexisting, but seemingly asymptomatic, preoperative scoliosis.

The above statement does not, however, say that patients with scoliosis above this threshold are guaranteed a poor outcome, only that it is clearly less likely that they will realize truly significant ODI improvement and be satisfied. In fact, no statistical difference was found among the three overall scoliosis groups with regard to ODI worsening (defined by a decrement of more than 6 points in 1-year

postoperative score). Only two in 22 patients above the scoliosis threshold fit this worsening category, a lower proportion than in the groups below the threshold, although not statistically significant. Also, individual patients above the threshold have done remarkably well. Case in point, the individual with the greatest amount of scoliosis in this study (ie, 55°) realized a 54-point ODI improvement, 6-point VAS improvement, a change in standing time from 15 to 180 minutes and walking time from 30 to 180 minutes at 1-year post-X-STOP. The probability of such an individual obtaining this result is less likely according to the data but is not precluded. A more typical Group 3 success is shown in the Figure.

Even further, the X-STOP is a low-risk procedure that can be done without a general anesthetic, in the lateral position (vs. prone that tends to be more stressful on the cardiovascular system), and usually as a one-night stay



Figure. Postoperative standing anteroposterior and lateral radiographs of a Group 3 patient with a 16-point improvement in Oswestry Disability Index at 1 year.

procedure that might obviate the need for a larger more morbid surgery when symptoms appear because of NIC. Future surgeries, if needed, are not compromised by the presence of an X-STOP. The posterior spinal elements are maintained, and the spinal canal is not breached during the procedure so that epidural fibrosis is not seen, and there is no risk of nerve root injury or dural tear. Therefore, in high-risk patients with surgical stenosis and multiple medical comorbidities or poor physiologic reserve, the X-STOP may often be the most attractive intervention despite the amount of overall scoliosis. The X-STOP should not, however, be construed as a procedure to treat scoliosis itself. When patients' symptoms stray from typical neurogenic claudication, the treatment should be addressed accordingly by other means.

Unlike overall scoliosis, segmental scoliosis at the treated level(s) was not associated with any of the outcomes in this study. Note, the two types of scoliosis were not mutually inclusive, as some patients with segmental scoliosis did not meet overall scoliosis requirements, and other patients with overall scoliosis did not have segmental scoliosis at the treated level. Although not statistically significant, there was a trend toward greater ODI improvement with increasing segmental scoliosis. We expected the opposite would be true that increasing segmental scoliosis would diminish ODI improvement as the X-STOP is a posterior midline interspinous device, and segmental scoliosis creates an asymmetric coronal tilt of the disc space that might not be sufficiently addressed. Those with the very best outcomes, however, had lower overall scoliosis but higher segmental scoliosis at the treated level. The data indicate that the X-STOP provides effective indirect decompression at a segment, regardless of the segmental scoliosis (at least up to 19°, the maximum seen in our study group). Thus, the only real coronal plane consideration should be overall scoliosis, as increasing segmental scoliosis does not appear to diminish outcome.

Walking and standing times at 1 year improved to a greater extent for overall scoliosis Groups 1 and 2 compared with Group 3. Note that even in Group 3, the least benefited by X-STOP implantation, the average 1-year postoperative walking time still improved by 16 minutes. Although VAS pain score statistically improved an average of 1.9 points for the entire cohort at 1 year ( $p=.0001$ ), it was not statistically different among the three groups. There was, however, a trend for lesser improvement for those with overall scoliosis greater than 25° (average 0.9 in Group 3 vs. 1.9 and 2.0 for Groups 1 and 2). The study data reflected greater variability in VAS scores within the three groups relative to the other outcome measures, a point that likely prevented realizing a statistical difference among the groups, particularly given the smaller number of patients in Group 3.

Ultimately, patient satisfaction questions were linked quite significantly to overall scoliosis. Patients with scoliosis greater than 25° achieved a satisfaction rate of between

55% and 64% versus those below 25° with a satisfaction rate between 76% and 92%. The satisfaction rates are different above and below the so-called overall scoliosis threshold, but the rates illustrate that even those patients with scoliosis above the threshold may be satisfied with the procedure and their results.

The outcomes and patient satisfaction rates achieved in Groups 1 and 2 are comparable to those reported in prior studies using the X-STOP or decompressive laminectomy to treat NIC [1–3]. Further, X-STOP results have been shown generally stable over time, up to 4 years at present [2]. In the present study, only 1-year data are presented, and this is valid because the result is a negative one. Only 18% of patients with overall scoliosis greater than 25° have achieved an ODI improvement of at least 15 points at this time point, even when treated for apparent symptoms of NIC. These results cannot be expected to improve, even if they remain stable, over the course of 2 or more years. Whether the X-STOP performs inferiorly in NIC patients with concomitant scoliosis above 25° or whether these individuals would have inferior outcomes no matter the form of treatment is unclear as the operative treatment of patients with adult scoliosis has been fraught with debate and major complication rates from 17% to 75%, particularly in older cohorts older than 65 years such as ours [9,10]. Nonetheless, the current, yet previously untested, recommendation to limit X-STOP use to those patients with scoliosis less than 25° appears valid. The decision to use the X-STOP in patients above this threshold must be considered in the context of patient function and expectation, a lower likelihood for success, or a lack of safe alternatives when severe comorbidities are present.

This study does have some important limitations. We focused on the coronal plane but not the sagittal plane. Also, there were inadequate numbers to stratify the groups by potentially important factors, such as global coronal or sagittal balance and presence and degree of spondylolisthesis or lateral listhesis. Those variables may need consideration in future studies.

In conclusion, use of the X-STOP in patients with overall spinal scoliosis of the lumbar degenerative type greater than approximately 25° must be considered in light of a lower likelihood for success, without increase in poor outcomes, but a greater chance of the remaining unchanged. In contrast, segmental scoliosis at a level to be treated is not a negative factor for outcome success.

## Conclusions

Overall lumbar scoliosis is an influential factor in the outcome success rate for NIC treatment by the X-STOP procedure, whereas segmental scoliosis of the treated segments is not. Patients with overall lumbar scoliosis curves greater than 25°, although not absolutely precluded, are at significantly lower chance of a satisfactory result from

the procedure, and selection of treatment must be put into the context of individual patient risk and alternative options for treatment.

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