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Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis

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Object. Interspinous process decompression (IPD) theoretically relieves narrowing of the spinal canal and neural foramen in extension and thus reduces the symptoms of neurogenic intermittent claudication (NIC). The purpose of this study was to compare the efficacy of IPD with nonoperative treatment in patients with NIC secondary to degenerative spondylolisthesis.

Methods. The authors conducted a randomized controlled study in patients with NIC; they compared the results obtained in patients treated with the X STOP IPD device with those acquired in patients treated nonoperatively. The X STOP implant is a titanium alloy device that is placed between the spinous processes to reduce the canal and foraminal narrowing that occurs in extension. In a cohort of 75 patients with degenerative spondylolisthesis, 42 underwent surgical treatment in which the X STOP IPD device was placed and 33 control individuals were treated nonoperatively. Patients underwent serial follow-up evaluations. The Zurich Claudication Questionnaire (ZCQ), 36-Item Short Form Health Survey (SF-36), and radiographic assessment were used to determine outcomes. Two-year follow-up data were obtained in 70 of 75 patients.

Statistically significant improvement in ZCQ and SF-36 scores was seen in X STOP device–treated patients but not in the nonoperative control patients at all postoperative intervals. Overall clinical success occurred in 63.4% of X STOP device–treated patients and only 12.9% of controls. Spondylolisthesis and kyphosis were unaltered.

Conclusions. The X STOP device was more effective than nonoperative treatment in the management of NIC secondary to degenerative lumbar spondylolisthesis.

KEY WORDS • **spinal stenosis** • **degenerative lumbar spondylolisthesis** • **neurogenic claudication** • **interspinous process decompression** • **steroid therapy** • **X STOP Interspinous Process Decompression System**

NEUROGENIC intermittent claudication is a specific symptom complex in which a patient is relatively asymptomatic while sitting but experiences progressive pain, numbness, or weakness of the legs while standing or walking.[36] To relieve symptoms, the patient may bend forward or return to the sitting position. The origin of NIC is thought to be dynamic neuroischemia; in the upright posture the severity of spinal stenosis reaches a critical impact that leads to neurological symptoms, whereas the condition is reversed by sitting or lumbar flexion.[20] One of the most common radiographically documented findings is degenerative spondylolisthesis, usually occurring at L4–5. In this condition, large remodeled facet joint articulations and vertebral translation result in spinal stenosis.

The initial standard treatment is nonoperative and includes administration of nonsteroidal antiinflammatory drugs. Brace therapy and physical therapy have little proven efficacy.[21,31,37] Epidural steroid agent injections are often prescribed prior to the consideration of surgery. In approximately one third of cases this treatment can result in sufficient relief to avoid surgery.[27]

Interspinous process decompression with the X STOP implant (St. Francis Medical Technologies, Inc., Alameda, CA) is a new technique in which an oval spacer is inserted between the spinous processes for the treatment of NIC resulting from lumbar spinal stenosis (Fig. 1).[18] By preventing extension or lordosis in patients with stenosis

Abbreviations used in this paper: IPD = interspinous process decompression; MCS = Mental Component Summary; NIC = neurogenic intermittent claudication; ODI = Oswestry Disability Index; PCS = Physical Component Summary; SF-36 = 36-Item Short Form Health Survey; VB = vertebral body; ZCQ = Zurich Claudication Questionnaire.

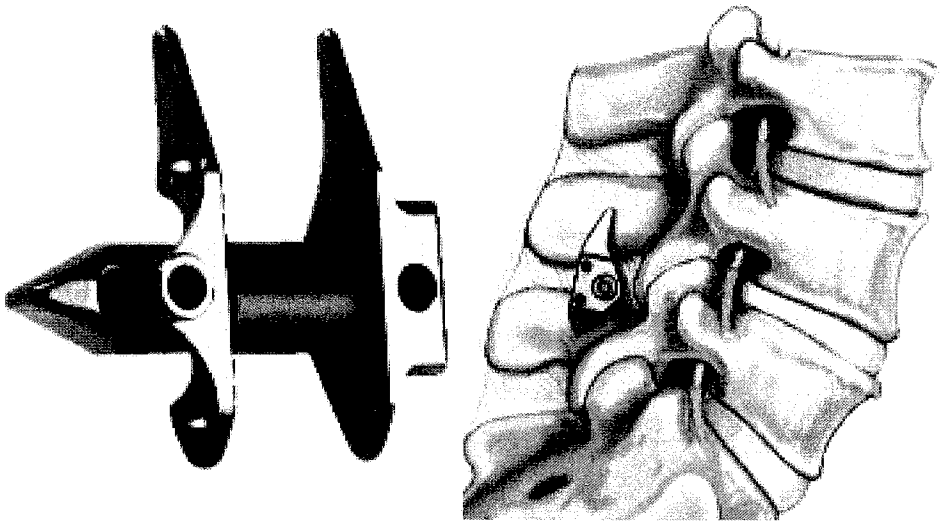

FIG. 1. *Left:* Drawing of the X STOP implant. *Right:* Schematic of the lumbar spine after placement of the X STOP device at L4–5.

while standing, IPD can prevent NIC. Zucherman, et al.,[40] have published the 2-year results obtained in a Food and Drug Administration trial in which they found a clinically significant improvement in symptom severity and physical function in 58 and 55% of patients, respectively. Furthermore, 71% of the patients were satisfied with the treatment. In a biomechanical study in cadaveric spines, Richards, et al.,[25] found that the X STOP IPD device significantly increased the canal area by 18%, the canal diameter by 10%, the foraminal area by 25%, and the foraminal width by 41%.

We hypothesized that the X STOP IPD device would improve function in patients with NIC due to spinal stenosis and degenerative spondylolisthesis. The purpose of this study was to measure the effectiveness of the X STOP device compared with nonoperative treatment in patients with degenerative spondylolisthesis and stenosis. We report the results obtained in patients enrolled in a randomized controlled study.

Clinical Material and Methods

Patient Cohort

A multicenter randomized clinical trial was performed at nine centers by 11 investigators to evaluate the safety and efficacy of the X STOP device. One hundred ninety-one patients with symptomatic one- or two-level lumbar spinal stenosis were randomized to undergo either IPD with the X STOP implant or nonoperative treatment. To be included in the study, patients had to be at least 50 years of age, had to have their symptoms relieved by sitting or flexion, and had to have completed at least a 6-month course of nonoperative treatment. Patients were excluded if they could not walk at least 50 feet and/or were unable to sit for at least 50 minutes, or if anterior translation greater than 25% was seen on imaging studies. One- or two-level degenerative spondylolisthesis was present in 75 patients, and this population formed the basis of our study. To be included in this spondylolisthesis cohort, anterior translation documented on standing lateral radiographs had to range between 5 and 25%.

After providing voluntary consent, patients were randomized by a centrally administered system to either the IPD treatment or control groups. All centers had received institutional review board approval and were approved as an Investigation Device Exemption study by the Food and Drug Administration. Prior to treatment, patients completed several outcome instruments. They completed the same instruments at 6 weeks and at 6, 12, and 24 months postoperatively. Standing anteroposterior and lateral radiographs were obtained during the same evaluations.

At the conclusion of the 2-year follow-up period, 98.9% of the treatment group and 92.1% of the control group were available for examination.

Nonoperative Treatment

Patients in the control group received at least one epidural steroid injection upon enrolling in the study. Additional epidural injections were administered at the discretion of the investigator. Patients also received nonsteroidal antiinflammatory drugs, analgesic agents, and physical therapy as needed.

Surgical Implantation of the X STOP Device

The correct interspinous location is determined by fluoroscopy. After administration of a local anesthetic, the X STOP implant is placed between the spinous processes while the patient is in the flexed right lateral decubitus position. The skin is incised, and the paraspinal muscles are subperiosteally elevated. The supraspinous ligament is carefully protected. Starting just posterior to the lamina, we place a dilator between the spinous processes from the right to left side. A sizing instrument is then inserted between the spinous processes and expanded until the supraspinous ligament is taut. Using a gauge on the sizing instrument, the X STOP device is sized for insertion

(range 6–14 mm). The device is then inserted, the locking wing connected, and the set screw locked. Patients are allowed to walk immediately and return to regular activities once the wound has healed (Fig. 2).

Radiographic Measurements

Standing lateral radiographs were digitized and stored as tagged image file format images. The percentage of slippage (spondylolisthesis) was measured using NIH imageJ (version 1.33; public domain). First, the length of the line (A/B; Fig. 3 *left*) was measured in pixels. This line was drawn along the superior endplate of the caudal segment extending from the anterior to posterior VB margin. A second line (C/D; Fig. 3 *right*) was measured; this was the length along the same line that extended anteriorly from the anterior border of the VB to the line intersecting orthogonally from the posterior margin of the cranial vertebral segment. The percentage of slippage was calculated as: spondylolisthesis = $(1-[CD/AB]) \times 100$. Lordotic angulation was measured using the technique proposed by Boos, et al.,[3] using the NIH ImageJ software. The measurements were made by three investigators not involved with the surgery and the sums were averaged. The mean standard error of the measurement was 0.12 and 0.96 for the percentage of slippage and angulation, respectively.

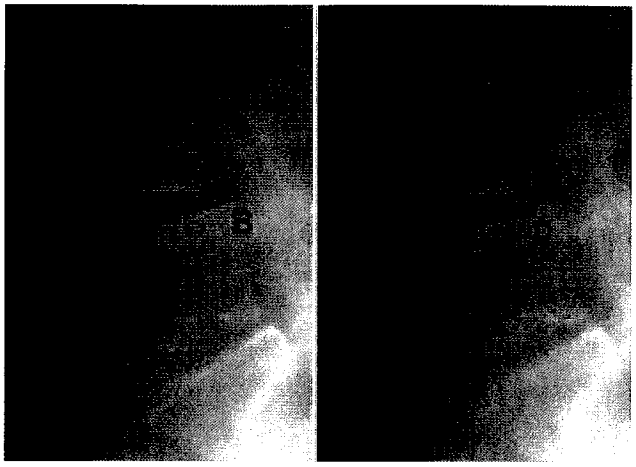

FIG. 3. Lateral radiographs demonstrating the technique for measuring spondylolisthesis. *Left:* The distance A/B is measured in pixels using NIH ImageJ along the line from the anterior superior corner to the posterior superior corner of the caudal vertebra. *Right:* The distance C/D along the same line from the anterosuperior corner to the point of intersection of an orthogonal line dropped down from the posteroinferior corner of the cranial vertebra. The percentage of vertebral slippage is determined using the following formula: % slippage = $(1-CD/AB) \times 100$.

Outcome Instruments

At baseline and at all follow-up intervals, patients completed the ZCQ, which consists of 18 questions relevant to three domains: symptom severity, function, and patient satisfaction.[32,33] The first two domains were combined and the scores normalized to 100, where 0 indicates no impairment and 100 the worst disability.[33] Patient satisfaction was scored on a scale from 0 to 5 with 0 reflecting the greatest satisfaction. Patient satisfaction was only assessed at follow-up evaluations. Additionally, patients' overall health status was assessed at all intervals by using the SF-36.

The ZCQ is a validated outcome instrument used to assess the severity of symptoms and the physical impairment caused by lumbar stenosis as well as a patient's satisfaction with treatment. It has been shown to be more sensitive than the ODI and the Oxford Claudication Score in this patient population.[22] The instrument can be normalized to 100 and responses analyzed similarly to the ODI. A minimally clinically significant improvement in the normalized ZCQ score is 15.[22] A positive response in patient satisfaction is a score less than 2.5.[33,34]

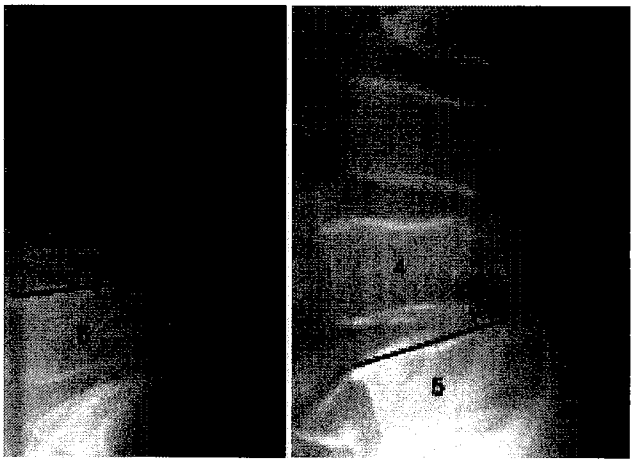

FIG. 2. Radiographs obtained in a 67-year-old woman with degenerative spondylolisthesis. *Left:* After treatment with the X STOP implant, her ZCQ score improved from 65.8 to 18.3%. The extent of spondylolisthesis increased by 2%. *Right:* Postoperative lateral radiograph showing the X STOP device in place.

Statistical Analysis

The Wilcoxon signed-rank sum was used to compare differences of continuous variables such as the percentage of VB slippage between treatment and control groups. For dichotomous variables, the Fisher exact test was used. Correlations were analyzed using Spearman rank coefficients. All statistical data were calculated using SAS software (SAS Institute, Inc., Cary, NC). A level of significance of 0.05 was used for all comparisons.

Cases in which laminectomy was required were considered failures in both groups. For statistical purposes, an intent-to-treat analysis was performed to test outcome variables at follow-up periods. No patients in the control group crossed over to the X STOP therapy group within the 2-year follow-up period. The overall clinical success was defined as: 1) an absolute 15-point improvement in the normalized ZCQ; 2) a patient satisfaction score less than 2.5; and 3) no additional surgery. All three criteria had to be achieved for the patient's treatment to be considered a success.

Results

Intergroup Comparison of Baseline Data

The baseline data were compared to assess equivalency between groups, and there were no significant demographic differences (Table 1). Additionally, no intergroup differences were noted in the percentage of spondylolisthesis, severity of ZCQ- and SF-36–measured disability, and the number of treated levels (Table 2).

Zurich Claudication Questionnaire–Measured Outcome

In the X STOP device group, the baseline ZCQ score was significantly improved at all postoperative periods. The baseline ZCQ score was 50.4 and at 2-year follow up it was 23.1 (Table 2). There was no significant improvement in the control group ZCQ score at any follow-up interval. The extent of improvement in the ZCQ score was significantly greater in the X STOP device–treated patients than in control patients at every interval ($p < 0.0001$).

Analysis of data obtained in the X STOP implant–treated group demonstrated immediate improvement that was sustained for at least 24 months, whereas in the control group only marginal improvement was demonstrated (Fig. 4).

Patient Satisfaction–Measured Outcome

Patient satisfaction was significantly different between the two groups at all follow-up intervals. At 2 years, the mean patient satisfaction score was 1.55 in the X STOP system and 2.8 in the control groups (Fig. 5). This difference was statistically significant.

The SF-36–Measured Outcome

The combined PCS and MCS domains were analyzed statistically. Analysis of the pretreatment SF-36 PCS scores indicated poor function in both groups compared with that measured in an age-matched healthy population. Significant improvement was seen in the X STOP implant–treated patients, whereas no change in baseline score was observed in the control patients (Fig. 6).

To examine the responsiveness of the ZCQ, a correlation between changes in ZCQ scores and changes in SF-36 PCS scores was performed; the Spearman rank coefficient analysis showed a statistically significant correlation (0.71 and 0.77, respectively) at the follow-up intervals (Fig. 7). Thus, the ZCQ score exhibited a similar response in functional change as the SF-36 score.

In either group the SF-36 MCS score was not significantly different than that in the normal asymptomatic population. Additionally, the MCS score did not change at 2 years in either treatment group.

Additional Surgery

Five patients in the X STOP device treatment and four patients in the control groups eventually required laminectomy or laminectomy and fusion, and their cases were considered to reflect treatment failures. No difficulties were noted when revising the X STOP implant when patients subsequently needed to undergo either laminectomy or laminectomy and fusion. The difference between surgical rates in the two groups was not statistically different.

Radiographic Results

In the X STOP device group, we documented no statistically significant change in the percentage of spondylolisthesis and kyphotic angulation at baseline and 2 years (Table 3). The extent of baseline slippage was 14.29% whereas at 2 years it was 14.19%. Lordotic angulation was 9.08 and 9.1° before and at follow-up examination, respectively.

Adverse Events

There was one procedure-related adverse event in the X STOP device group, an incisional complication that resolved after 1 week of oral antibiotic therapy. There was one device-related adverse event, a malpositioned implant that was later detected on radiographic examination. The

TABLE 1

Summary of preoperative data obtained in both groups of patients with NIC

Variable	Patient Group: X STOP	Patient Group: Control	p Value
no. of cases	42	33	
mean age (yrs)	71.4	68.5	0.192
range	52–82	50–88	
mean height (in)	66.3	65.7	0.568
range	60–74	60–75	
mean weight (lbs)	173.7	166.7	0.443
range	115–260	98–260	
males (%)	45.2	33.3	0.348
females (%)	54.8	66.7	
symptoms (%)			
≤2 yrs	35.7	36.4	1.000
>2 yrs	64.3	63.6	
retired (%)	64.3	60.6	0.812
Workers' Compensation (%)	2.4	3.0	1.000

TABLE 2

*Summary of outcomes in the X STOP IPD–treated and control patients**

	Patient Group: X STOP	Patient Group: Control
ZCQ		
baseline	50.40 ± 2.04	51.26 ± 2.39
2 yrs	23.05 ± 3.14	47.40 ± 3.18
SF-36 PCS		
baseline	31.53 ± 1.68	28.19 ± 1.29
2 yrs	41.19 ± 1.97	28.14 ± 1.10
SF-36 MCS		
baseline	52.06 ± 1.76	49.92 ± 1.78
2 yrs	56.29 ± 1.25	49.66 ± 2.22
patient satisfaction		
2 yrs	1.55 ± 0.11	2.80 ± 0.18
clinical success (%)		
2 yrs	63.4	12.9

* Data are given as means ± standard error of the means except where noted.

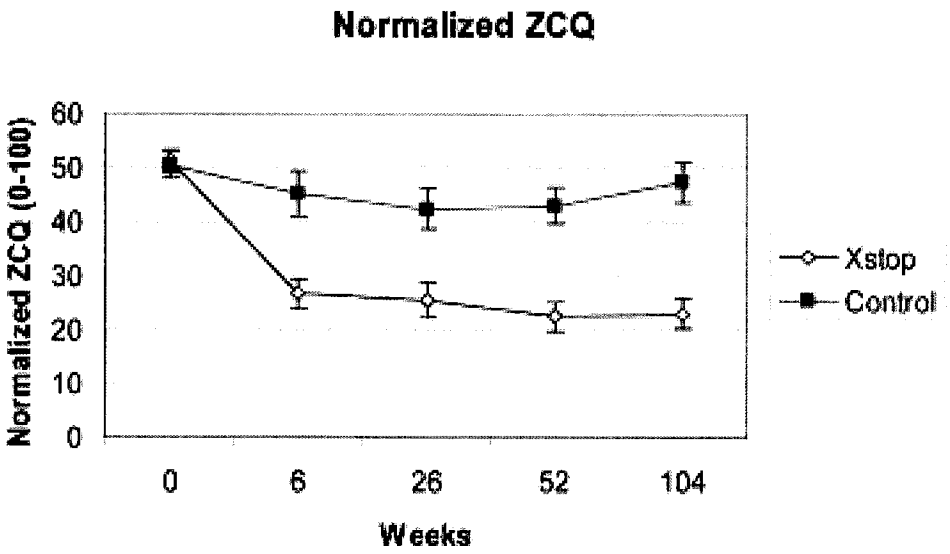

FIG. 4. Graph showing the ZCQ results at each time interval for X STOP device–treated and control patients. Lower scores represent better outcomes. Statistically significant improvement was documented at each follow-up interval in the X STOP implant group only. At each follow-up interval, the X STOP system results were significantly better than the control results.

surgically treated level was asymptomatic, and additional medical treatment was deemed unnecessary. There was no evidence of any nerve injuries or neurological deterioration as a result of the X STOP implantation. One adverse event occurred in a control individual: a reaction to the epidural steroid injection. In six patients in the control group the ZCQ score worsened by greater than 15%.

Overall Clinical Success

Overall 2-year clinical success, defined as a case in which all three criteria (15-point ZCQ improvement, a patient satisfaction score < 2.5, and no further surgery) were met, was demonstrated in 63.4% of X STOP implant–treated patients and 12.9% of control patients (Table 4). This difference was highly statistically significant.

Discussion

Neurogenic claudication is a specific symptom complex that has been described by Verbiest.[36] The typical symptoms are pain, numbness, and weakness in the buttock and legs that progressively worsens as the individual stands or walks. Eventually the patient will need to sit, lie down, or bend forward to feel relief from the discomfort. While sitting, the individual is generally asymptomatic.

TABLE 3
*Summary of radiographic data obtained in both groups**

Measurement Interval	% Slippage	Lordotic Angulation (°)
baseline	14.29 ± 5.21	9.08 ± 5.43
follow up	14.17 ± 6.71	9.10 ± 4.87
difference	0.37 ± 5.65	0.21 ± 4.2

* Data are presented as the means ± standard deviations. Significant differences between the two intervals were absent.

The presumed cause of NIC is that as the spinal column extends while the individual is standing or walking, the joint capsules, ligamentum flavum, and intervertebral disc buckle into the spinal canal, thus increasing stenosis beyond a critical level. To compensate, patients characteristically walk with a flexed lumbar spine, bend forward or lean over, for example against a shopping cart, because they have discovered that this can relieve their symptoms.

The spinal canal is well known to change dimensionally during flexion and extension. In extension, its midsagittal diameter decreases by more than 2 mm, the canal cross-sectional area by 25 to 40%, and the intraforaminal area by 40%.[30] The ligamentum flavum is an important

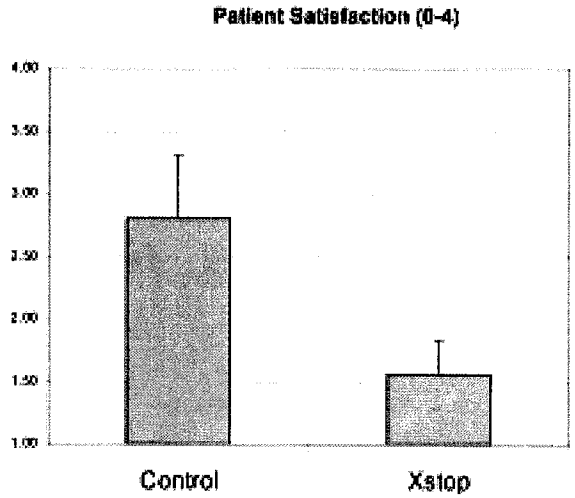

FIG. 5. Bar graph demonstrating patient satisfaction scores. Lower scores represent better satisfaction. The X STOP device–treated patients were significantly more satisfied than the control patients at each time point.

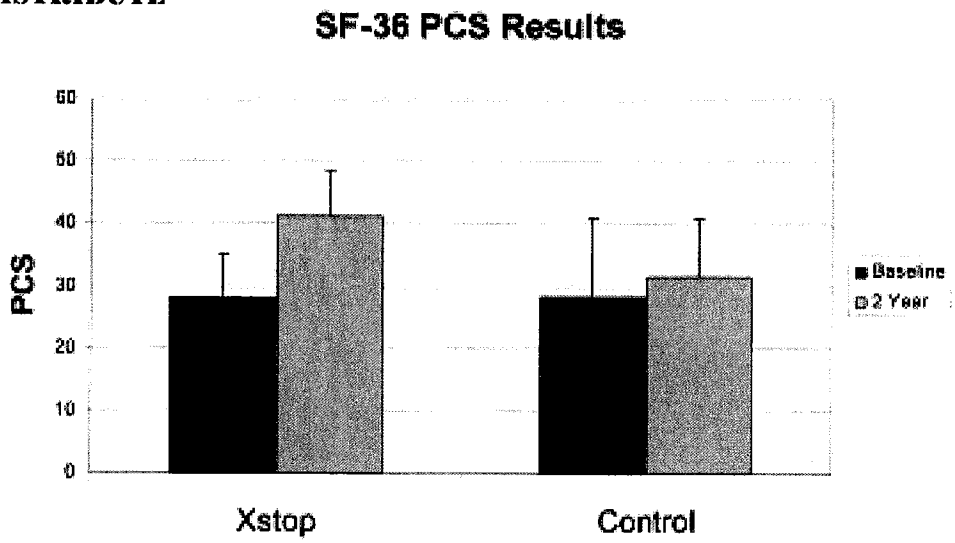

FIG. 6. Bar graph showing SF-36 PCS scores at baseline and follow up in both groups. Higher scores represent better physical status. Statistically significant improvement was demonstrated in the X STOP system–treated patients only.

contributor to this process and in extension increases by more than 2 mm in thickness as a result of infolding[4,9,24] Other dynamic changes that narrow the spinal canal occur secondary to bulging of the intervertebral disc and subluxation of facet joints and VBs. This observation has been confirmed by in vivo investigations. Schmid and colleagues[29] have performed dynamic upright magnetic resonance imaging studies to assess changes in cross-sectional area. They found that the spinal canal area increased by 19.2% in flexion and decreased by 23.3% in extension. Additionally, an increase in epidural pressure occurs during extension. Ultimately, the increased pressure leads to ischemia and impaired neural function resulting in NIC symptoms.[19,35]

One treatment strategy for symptomatic NIC has been to avoid extension by applying a brace. Unfortunately, this method is rarely acceptable or efficacious.[10] Prevention of local extension at stenotic areas is a novel concept, but success depends upon the stability of the implant and the strength of the spinous process. Yerby, et al.,[38] have reported that the mean failure strength of the L-3 spinous process is 1033 $\pm$ 505 N when loaded on the caudal surface and 765 $\pm$ 374 N for the L-4 spinous process when loaded on the cranial surface. These failure loads were significantly higher than the mean in situ load on the X STOP system, which was 109.5 $\pm$ 65.3 N.

The authors of cadaveric and in vivo studies have demonstrated that IPD with the X STOP device eliminates the reduction in the cross-sectional area that occurs in extension. Lee and colleagues[17] have evaluated 10 X STOP implant–treated patients with pre-and postoperative magnetic resonance imaging. They reported overall clinical success in seven patients. The postoperative dural sac cross-sectional area increased by 23% and the neural foraminal area by 36%. Their findings correlate with the cadaver studies conducted by Richards, et al.,[25] who noted an increase in canal area of 18%, canal diameter of 10%, and foraminal area of 25% after implantation of the X STOP device.

Several methods for evaluating outcomes in patients with spinal stenosis have been developed. The ZCQ is a validated outcome measure that may better evaluate elderly patients with symptoms of intermittent neurological compression than patients with other spinal disorders.[22] The instrument consists of seven questions pertaining to the severity of disease, five to function, and six to patient satisfaction. Normalization to a scale from 0 to 100 allows statistical comparison using methods similar to those of the ODI and Roland–Morris Disability Questionnaire. The ZCQ can be used to compare a patient's baseline and follow-up status directly and by a dichotomous score related to success or no success. Pratt, et al.,[22] tested the reliability of the ODI, the ZCQ, the Oxford Claudication Score, and a walking test in 29 patients with lumbar stenosis. They found that the ZCQ was the most reliable instrument in this specific population. The ZCQ was responsive to the treatment of lumbar spinal stenosis, and a 15-point improvement for a single case was found to be clinically significant; however, statistical improvement occurs with only a six-point improvement if there is a minimum of 20 cases. Based on the work of Pratt, et al., we selected a 15-point improvement in the normalized ZCQ score along with a patient satisfaction score of less than 2.5 (as defined by Stucki, et al.,[33]) to define success in an individual case. Pratt, et al., demonstrated that patient satisfaction correlated well with functional improvement, which was observed in the present investigation. We used these same criteria to determine overall success on the ZCQ. These stringent criteria may have resulted in the overall poor results seen in the nonoperative treatment groups. Similar to the X STOP device–derived results observed in our study, Pratt, et al., reported that in 11 (65%) of 17 patients there was significant improvement in ZCQ score following laminectomy.

The outcomes associated with nonoperative treatment in patients with degenerative spondylolisthesis are poorly documented. In the present study, only 13% of the cases were considered to reflect clinical success based on our

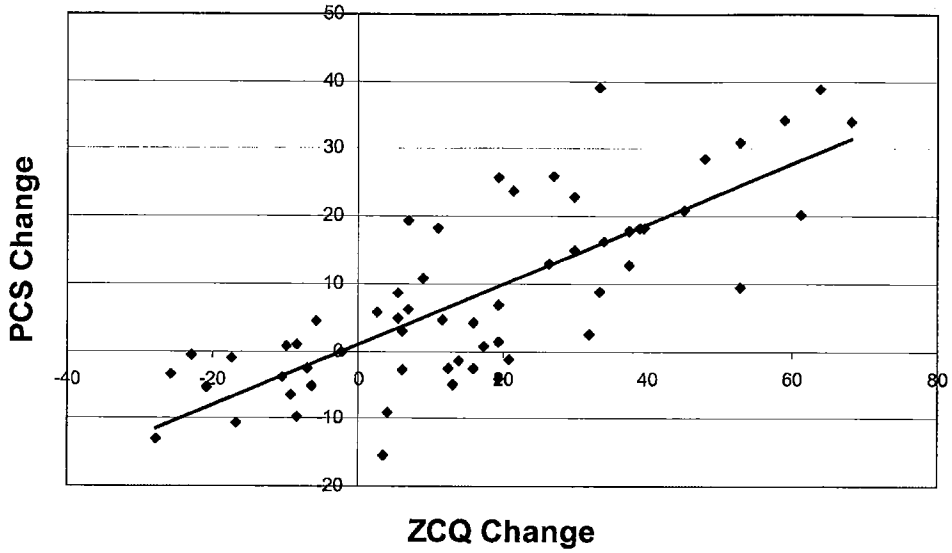

FIG. 7. Scatterplot demonstrating correlation of change between the ZCQ and SF-36 PCS scores in all patients at 24 months. Spearman rank coefficient value was 0.77, indicating a strong correlation between change in the SF-36 and ZCQ scores.

criteria. The authors of several randomized studies have demonstrated a significantly more favorable response (that is, increased pain relief and decreased analgesic medication usage) in patients who received steroid injections compared with control individuals who received a placebo.[5,6,26,28] Other investigators, however, have obtained less favorable results. Rivest, et al.,[28] for example, reported that only 38% of their patients experienced pain relief at 2 weeks. The poor results in the present study may be explained by attributing the pain in patients with NIC to neuroischemia rather than inflammation, making epidural steroid injection less likely to be effective. This observation was surprising given the number of patients in whom these injections are used. Although our criteria were stringent, the absence of SF-36 PCS–based success confirmed the similar lack of improvement, which has been shown to be responsive to such treatment in other lumbar surgery studies. Not surprisingly, the MCS scores were not affected by symptoms of NIC compared with those obtained in age-matched healthy individuals and did not respond to either treatment.

In this study we documented significant improvement in ZCQ and SF-36 PCS scores in patients in whom the X STOP device was implanted. The study was not designed to include patients undergoing decompression with or without fusion. Katz, et al.,[15] prospectively studied patients who underwent laminectomy by administering the ZCQ. In their series, symptom severity significantly improved in 63% of the patients, physical function significantly improved in 59%, and overall satisfaction was noted by 72%; all of these percentages are comparable with those in the present study. In assessing ZCQ reliability, Pratt, et al.,[22] found that scores in laminectomy-treated patients improved from 54.5 to 39.3, whereas in our series scores improved from 50.4 to 23.1. Recently, Ghogawala and associates[8] reported SF-36 PCS results in 36 patients treated by laminectomy and laminectomy with fusion. At 2 years the overall increase in the PCS score reflected improvement (30.4 at baseline to 40.8 at 2 years). This finding is in close agreement with the results in our series (28.1 at baseline to 39.2 at 2 years). Additionally, the overall success rate of X STOP treatment in the present study were similar to surgery-related outcomes reported by Johnsson and colleagues,[11] Amundsen and associates,[1] and Atlas, et al.[2] The use of common outcome instruments such as SF-36, ZCQ, and patient satisfaction allow a more accurate comparison among studies.

A weakness of the study was that the protocol for nonoperative treatment was not controlled. All patients, however, received epidural steroid injections, although the dose, route of delivery, and frequency of treatments were not standardized. Other factors such as physical therapy and medical comorbidities also were not controlled. These variables, however, are similar to problems in other studies in terms of outcome after epidural steroid injections.

In the present study the cohort was selected from a randomized controlled trial in which the safety and efficacy of the X STOP device were evaluated. One-and two-year results of the entire group have previously been reported by Zucherman, et al.[39,40] In the current study we only examined cases involving degenerative spondylolisthesis. These patients may have a different prognosis and often

TABLE 4

*Summary of overall clinical success rates**

Group	No. of Cases	% Success
control	42	12.9
X STOP	33	63.4

* See text for definition of clinical success. Significant differences were observed between the two groups.

require different treatments than patients with other forms of stenosis because many more patients with spondylolisthesis will undergo decompression and fusion. Evaluation of the results indicates that the X STOP implant led to significantly greater improvement in patients' pain and function than nonoperative treatment.

The radiographic results were reassuring. There was no increase in spondylolisthesis in the X STOP device–treated patients during the 2-year follow-up period. A criticism of IPD is that it results in lumbar kyphotic angulation and flat-back syndrome. A decrease in lumbar lordosis was not observed. In a previous study by Zucherman, et al.,[39] X STOP implant–treated patients suffered a loss of lordosis at the treated level but the overall L1–S1 lordosis was not affected. Thus, there appeared to be a compensation that occurred at other levels for the 2° increased angulation at the treated levels. Unfortunately, follow-up radiographs in the control group were not obtained, precluding comparison of the 2-year change in vertebral slippage or deformity.

Although clinical success was documented in only 63.4% of the patients, this incidence needs to be put into context. The placement of the X STOP system is performed after the administration of a local anesthetic and as an outpatient procedure. Symptomatic relief is quick and late-onset deterioration in patients in whom surgery was initially successful is relatively rare. Complications are few and are easily treated. Complications related to laminectomy and especially laminectomy combined with fusion are significant and have been published elsewhere.[7,12–14,16,23] If the X STOP treatment fails, then conversion to laminectomy or laminectomy/fusion is not affected by the device.

Statistical analyses even in randomized studies are difficult when other interventions occur that affect outcome. In our study, five patients in the X STOP device group and four patients in the control group underwent laminectomy, and the case of each patient was considered a treatment failure. The continuous variables in these cases were analyzed by intention to treat. We also accounted for the poor outcomes by including the last result recorded prior to surgery as the final outcome. Using these analyses, only a treatment effect and no difference in the statistical results was present.

As with all spinal surgeries, the exact indications for the X STOP treatment need to be followed to establish which lead to optimal clinical results. Patients enrolled in this randomized study all suffered from classic NIC; that is, they were relatively pain free while sitting, and the symptoms only developed when they were standing or walking. Additionally, one or two vertebral levels were treated and greater than 50% canal compromise was present in at least one level. Because of the variable size and strength of the S-1 spinous process, the X STOP implant was not evaluated at the L5–S1 level. Osteoporosis was not a contraindication, although a history of an osteoporotic fracture was.

Conclusions

In a randomized controlled study of patients with NIC secondary to degenerative spondylolisthesis, X STOP IPD device treatment resulted in significantly greater improvement in pain status and satisfaction than epidural steroid therapy. Few complications were noted. The extent of postoperative sponylolisthesis correction was maintained, and a mean increase of only 2° in kyphosis was noted at the treated level.

Disclosure

Dr. Anderson is a consultant for and stockholder of the company manufacturing the X STOP device.

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