Chapter 35

Clinical Results of IDE Trial of X-Stop Interspinous Systems

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Elizabeth Yu and James F. Zucherman

35.1 Lumbar Spinal Stenosis

Lumbar spinal stenosis is narrowing of the spinal canal that results in compression of the cauda equina. Stenosis may be present focally at a single level or at multiple levels. It may be due to congenital/developmental stenosis, acquired/degenerative stenosis, or a combination of the two.[1] When stenosis is secondary to degenerative changes, presentation is most common in the population over age 50.

Neurogenic intermittent claudication is the clinical manifestation of lumbar spinal stenosis. Symptoms were first described by Verbiest in 1954 in a case report of seven patients. All had spinal stenosis. Symptoms described included weakness in the bilateral lower extremity and numbness that were present with walking or standing and relieved with rest.[2] Relief from neurogenic intermittent claudication results from forward flexion and expansion of the spinal canal as well as the neural foramen. Treatment of symptomatic lumbar spinal stenosis ranges from nonoperative to operative treatment. The natural history of spinal stenosis is variable with 45% of patients remaining stable, 15% of patients improving, and 30% of patients declining.[3]

35.2 Treatment

Nonoperative treatment includes medication, bracing, physical therapy, as well as epidural steroid injections. Weinstein et al conducted a multicenter randomized control trial as well as an observational cohort group to compare nonoperative treatment with surgical decompression. The multicenter study included 13 centers within the United States with a follow-up of up to 4 years. Outcomes were measured at 6 weeks, 3 months, 6 months, and yearly with outcome measures of Short Form (SF)-36 and Oswestry Disability Index (ODI) scoring. The study found that patients who had failed 3 months of conservative treatment for symptomatic lumbar spinal stenosis had significantly improved pain scores and function up through follow-up at 4 years when treated with surgical decompression compared with the continued nonoperative group.[4]

35.3 Operative Intervention

The goal of operative intervention is decompression of the thecal sac. Multiple procedures have been described to include, but not be limited to, laminectomy, laminotomy, and insertion of an interspinous process distraction system. This chapter focuses on the application of the interspinous process distraction system, specifically the X-Stop Spacer (Medtronic, Minneapolis, MN) (▶ Fig. 35.1).

Fig. 35.1 Polyether-ether-ketone X-Stop implant. (Images provided by Medtronic, Inc. X-STOP, device incorporates technology developed by Gary K. Michelson, MD.)

The X-Stop is designed to limit terminal extension at stenotic levels of the lumbar spine and relieve symptoms of lumbar spinal stenosis. It is targeted toward patients with intermittent neurogenic claudication. Patients would have failed nonoperative treatment and find relief with flexion. On-label indications are for those over 50 years of age, greater than 50 minutes continuous sitting tolerance, and ability to walk more than 50 feet.

Multiple studies have reviewed the risks and benefits of the X-Stop. Zucherman et [1]al conducted a multicenter prospective randomized study looking at the first year's results. Nine centers participated in the study with 200 patients randomized from May 2000 to July 2001. Patients included had either a magnetic resonance imaging (MRI) scan or a computed tomographic (CT) scan that demonstrated one or two levels of stenosis. One hundred patients were randomized into the X-Stop group and 91 were randomized into the nonoperative group. Nine patients withdrew from the study after their randomization. Nonoperative treatment included one or more epidural steroid injections, nonsteroidal anti-inflammatory medication, analgesics, as well as physical therapy and/or bracing. Mean age was 70 in the X-Stop group and 69 in the nonoperative group. Average duration of symptoms between the two groups was between 3 and 4 years. Outcomes were measured using the Medical Outcomes Study Short Form-36 (SF-36) and the Zurich Claudication Questionnaires (ZCQ). Patients were seen at 6 weeks, 6 months, and 1 year posttreatment. Preoperative ZCQ scores were not statistically different between the two groups. At each follow-up milestone, patients randomized to the X-Stop group had significantly improved ZCQ and SF-36 scores compared with the randomized nonoperative group. The authors con-

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cluded that at 1 year, patients with neurogenic claudication significantly improved with X-Stop treatment compared with nonoperative treatment with similar reoperation rates.[5]

The same group reviewed their results at 2 and 4 years.[6,7] At 2-year follow-up, 93 of the 100 X-Stop patients and 81 of the 91 nonoperative patients were available for follow-up. Six of the 93 patients in the X-Stop group and 24 of the 81 patients treated nonoperatively underwent decompression surgery by 2 years. When reviewing imaging studies, 96% of the X-Stop group had maintenance of distraction at 2 years. ZCQ score improved in 48.4% of the X-Stop group compared with 4.9% of the nonoperative group at 2-year follow-up.[7] The same group also assessed the quality of life of the patients at 2-year follow-up using the SF-36 scoring. They gathered the bodily pain, general health, mental and physical component, physical functioning, emotional and physical roles, and the social function aspect of the outcome form. At 2 years, they found statistically significant improvement in all areas except general health, emotional role, and mental component when compared with the nonoperative group. There was improvement in the majority of the quality of life assessment, to include the physical component as well as physical function and role, improvement in bodily pain, mental health, and social function.[8]

At 4 years, [1] Kondrashov et al noted 18 patients from the original study randomized to the X-Stop were available for follow-up. Average follow-up was 51 months, and outcomes were measured based on ODI scores. Improvement was noted when comparing preoperative ODI of 45 (range, 20–80) and postoperative ODI of 15 (range, 0–36). The authors noted that the ODI and ZCQ (also known as the Swiss Spinal Stenosis Questionnaire) outcome scores have been shown to be similar for outcome measures of spinal stenosis patients.[9] They concluded that the X-Stop has lasting effects.[6]

Five-year prospective data from a multicenter study, to include [2] Zucherman et al, have been gathered and analyzed. Twenty-eight patients with a minimum of 5-year follow-up had undergone X-Stop placement with the same criteria as the original X-Stop study discussed previously. The average age was 67.5 years. The ZCQ was used for outcome measures. Preoperative outcomes compared with postoperative outcomes demonstrated an average score improvement of around 1 point for both the symptom severity and physical function, with a change of 0.5 points defined as clinically important. There was one displaced X-Stop that was revised within the study time period. The authors concluded that neurogenic claudication treated with the X-Stop provides improved patient outcomes out to 5 years thus far.[10]

35.4 Biomechanics/Design Rationale

Biomechanical and cadaveric studies have been conducted assessing the central canal and foraminal space changes with flexion and extension of the spine. [3] Schmid et al reviewed MRI scans of 12 volunteers with a mean age of 28. [4] No patient had an abnormal MRI scan, to include disc pathology. MRI scans were obtained in the seated upright neutral, seated upright flexed, seated upright extended, and supine extended positions. Two radiologists read the MRI scans and measured the anterior-posterior diameter of the central canal, cross-sectional area of the canal at the disc and pedicular levels, as well as the cross-sectional area of the neural foramina. All but two reads were within 10% of each other. In their results, they found there was a mean decrease of cross-sectional area of 16.4% when comparing seated upright flexion and extension at the level of the L4–L5 disc, whereas there was no change in cross-sectional area at the pedicular level. In views of the ligamentum flavum, there was an approximately threefold increase in thickness with seated upright extension compared with flexion. In assessments of the neural foramen, there was a mean decrease of cross-sectional area of 23.2% in comparisons of seated upright flexion and extension at each disc level of L1 to S1. There was a 19.2% increase in cross-sectional area in comparisons pf the seated upright neutral position with the seated upright flexion position. The authors concluded that the position of the spine, particularly in seated upright extension, can result in changes in the area of the spinal canal and neural foramen.[11] Fujiwara et al studied cadaveric models and assessed the six degrees of motion of the lumbar spine.[12] The average age of the cadavers was 69. All muscle was removed, leaving the ligaments, disc, and neural elements. Biomechanical testing included flexion, extension, lateral bending, and rotation. Cross-sectional area of the foramen was measured using CT scans. Flexion increased the foraminal area by 11.3%, and extension decreased the area by 12.0%. Lateral bending decreased the area by 8.4% and opened the contralateral foramen by 8.0%. Rotation showed a decrease in area of 5.7% and opening on the contralateral side of 6.5%.[12]

The effect of the X-Stop on foraminal and canal area has been studied. Twenty-six patients with lumbar spinal stenosis underwent X-Stop placement with review of preoperative and postoperative MRI. The mean age was 71. The MRI scans were obtained with the patients in the erect position, sitting neutral, and flexion and extension positions. The authors noted a [5] statistically significant increase in the spinal canal area in the erect and seated upright neutral position compared with the preoperative area in single-level X-Stops. At double-level X-Stops, there was a significant increase in area in the erect and seated upright extension position. When looking at the neural foramen, they noted increased area in both the seated upright flexion and extension positions.[13] Another study had similar results. A review of 10 patients who underwent the X-Stop application and were followed for a minimum of 9 months demonstrated a 22.3% increase in the cross-sectional area of the dural sac and a 36.5% increase in the cross-sectional area of the neural foramen from preoperative to postoperative MRI.[14] [6] Zucherman et al's group has also assessed their patients' MRI outcomes. Nine patients underwent both preoperative and postoperative MRI evaluation at an average of 6 years postoperatively. MRI was used to assess the average canal and neural foraminal area. Disc height and end plate angles were also measured. There was a statistically significant increase in canal area from 1.27 cm^2 to 1.42 cm^2 and a foraminal area increase from 0.54 cm^2 to 0.97 cm^2. There was no difference in disc height or end plate angles.[15]

Concerns have been raised as to the effect of sagittal balance secondary to the device. [7] Siddiqui's group reviewed the same 26 patients noted earlier and looked at the effects of motion and disc height and angulation on the patients with X-Stops. Preoperative and postoperative MRI scans were obtained in the

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standing, seated upright neutral, flexion and extension, and supine positions. Disc heights were measured in the seated flexion and extension positions as well as supine and erect positions. Lumbar motion was measured from the superior end plates of L1 and S1 in the upright seated extension and flexion positions. The authors' results showed that there was no significant difference in lumbar curvature pre- and postoperatively. There was a decreased range of motion in the caudal level of a two-level X-Stop placement. There was no change in range of motion for a one-level X-Stop placement. There was no significant change in the anterior or posterior disc height pre- and postoperatively. The authors concluded that there was no significant change in the sagittal kinematics with X-Stop placement on the lumbar spine.[16] Schulte et al conducted a prospective study of 20 patients who underwent an X-Stop placement.[17] All patients had a standing flatback radiographic series done, and the sagittal balance was assessed preoperatively and postoperatively. The average age of the patients was 68. One-level X-Stop was performed in 5 patients, two-level X-Stop in 14 patients, and three-level X-Stop in one patient. Sagittal balance was found to have improved in 16 of the 20 patients and declined in 4 of the 20 patients. Mean change in sagittal balance was − 2.0 cm.[17]

Lindsey et al additionally reviewed the results of the range of motion of the lumbar spine and the adjacent lumbar levels with X-Stop implantation.[18] Seven cadaveric models were employed. L2–L5 were studied with the donors ranging in age from 17 to 55. Flexion, extension, lateral bending, and axial rotation were assessed. One-level X-Stop was performed at each level independently. It was found that the range of motion of extension was significantly reduced at L3–L4 and L4–L5 levels of implantation. The overall range of motion of L2–L5 in flexion and extension was also significantly decreased. There was no significant change in axial rotation or lateral bending with and without the implant. The authors therefore concluded that the motion segments adjacent to the X-Stop levels are not significantly affected kinematically.[18]

35.5 Biomechanical Effects of the X-Stop

The X-Stop device was devised as a safer, less invasive approach for treatment of neurogenic intermittent claudication from lumbar spinal stenosis. Because of its relative safety, rapid recovery rate, and ease of administration under local anesthesia, many elderly, osteoporotic, and fearful patients are especially attracted to the procedure as are their surgeons. The insertional load to failure of the X-Stop and the spinous process load to failure were studied by Talwar et al.[19] Four cadaveric specimens were used to study the insertional load of L3–L4 and L4–L5. The maximum load and mean load of insertion of the device were measured. Seven cadaveric specimens were used to measure the load to failure of the spinous process when the device was loaded in the cranial, middle, and caudal portion of the spinous process. Bone mineral density was measured on each specimen. The average age of the specimens was 64. The authors found that the mean lateral insertional load of the X-Stop was 65.6 N, and the mean spinous process load to failure was 316.9 N. The mean load to failure at the area of the spinous process was not significantly different. They did find a linear correlation between the mean load to failure of the spinous process and the square of vertebral bone mineral density. The authors concluded that the mean load to failure of the lumbar spinous process is over four times the mean lateral insertional load of the X-Stop, concluding that the technique of device placement is relatively reliable when bone mineral density is greater than − 2.8.[19]

Intervertebral disc pressure as well as facet loading and how they are affected have been studied in the cadaveric model. Swanson et al used pressure transducers on eight cadaveric lumbar spines ranging in age from 56 to 80.[20] Each disc from L2 through L5 was subjected to 700 N of axial pressure with intradiscal pressure measured with the spine in neutral, extended, and flexed positions. For the bending moment, 7.5 Nm was used. An X-Stop was then placed between L3–L4 and the test was repeated. The authors reported that there was a significant decrease in the intradiscal pressure at the posterior annulus of L3–L4 (level of implantation) as well as a decrease in intradiscal pressure in the nucleus in the neutral and extended positions. There was no significant change in the intradiscal pressures of L2–L3 and L4–L5.[20]

Wiseman et al assessed the pressure on the facet joints in extension with implantation of the X-Stop.[21] Seven lumbar cadaveric models were used to assess the L2–L3, L3–L4, and L4–L5 facet joints. All specimens were axially loaded with 700 N, and facet joint pressures were measured using pressure films. Then a 15 Nm extension moment was applied and the pressure film was remeasured. An X-Stop was then placed at L3–L4 and the models were retested. Results showed that the X-Stop significantly reduced the mean pressure, contact area, and force at L3–L4 by 39%, 46%, and 67%, respectively. The adjacent facet joints did not change at L2–L3. The authors concluded that the X-Stop decreases the facet load at the implant level and does not affect the load at adjacent facet levels.[21]

35.6 Economic Considerations

The cost of the treatment of lumbar spinal stenosis has been reviewed. Skidmore et al compared the cost of the nonoperative treatment versus X-Stop and laminectomy versus X-Stop for lumbar spinal stenosis.[22] A literature review was conducted as well as formulation of a cost-effectiveness analysis based on a multicenter, randomized study of 131 patients. Data regarding medical reimbursement, Medicare reimbursements, and estimated medical costs were gathered for a 2-year period. Quality-adjusted life years were calculated as well. The authors concluded that, for moderately affected patients with lumbar spinal stenosis, X-Stop placement as an outpatient was more cost-effective than a laminectomy and nonoperative treatment.[22]

Burnett et al, on the other hand, also compared the treatment of nonoperative care, decompression laminectomy, and X-Stop placement over 2 years.[23] A literature review was conducted and a cost-effectiveness model was created to look at the direct health care costs with the use of mean case numbers and reimbursements of 16 states as well as the medical reimbursement costs of the three treatment options. Outcomes were measured using quality-adjusted life years. Laminectomies were considered inpatient procedures, and X-Stops were considered outpa-

tient procedures. The two surgical groups also had the additional cost of the nonoperative group. At 2 years, the authors concluded that laminectomy was the most effective treatment, followed by X-Stop and lastly nonoperative treatment.[23]

Kondrashov et al retrospectively reviewed 18 patients with X-Stop placement at one or two levels with age-matched patients who underwent laminectomy decompression.[24] Both groups had similar-length follow-up of a little more than 4 years. The X-Stop procedure was performed on an outpatient basis. Average hospital costs for each procedure were assessed. The authors concluded that, when directly comparing the X-Stop and laminectomy procedures and their perioperative costs to the hospital, a single-level X-Stop is approximately one third the cost of a single-level laminectomy, and a double-level X-stop is approximately half the cost of a two-level laminectomy.[24]

35.7 Complications

Complications from the use of the X-Stop have been reviewed. Bowers et al retrospectively reviewed all patients in their institution who underwent an X-Stop placement.[25] Thirteen patients with moderate or severe spinal stenosis had X-Stop application at L4–L5 and L3–L4. The average age of the patients was 75. All but one patient had regular follow-up intervals within 2 years postoperatively. All patients were contacted at 4 years postoperatively. All patients had improvement in back and leg pain after surgery; however, 10 patients' pain returned (77%). The authors noted complications with the X-Stop included three patients with spinous process fractures with resultant laminectomy with fusion. Two patients had new radiculopathies, of which one was at the X-Stop level and the other was at the adjacent level. Four patients required subsequent laminectomy decompressions. Two patients were counseled on laminectomy. The authors concluded that they had an 85% complication rate, that X-Stop may not be as beneficial for patients with moderate to severe spinal stenosis, and that careful patient selection is imperative.[25]

Survival analysis was retrospectively assessed by Tuschel et al at a single institution, where 46 patients underwent a total of 61 X-Stop procedures.[26] The mean age was 68.2, with 31 single-level X-Stop and 15 patients with two-level X-Stops. The mean follow-up was 34 months. Five patients did not meet follow-up criteria, and 14 patients underwent revision surgery by latest follow-up. Twenty-nine patients with X-Stops remained for review. VAS, ODI, and SF-36 (physical component summary score) scores significantly improved, but the SF-36 (mental component summary score) did not significantly improve from preoperative to postoperative. When asked to rank satisfaction, 47% were very satisfied, 37% were somewhat satisfied, and 16% were not satisfied. Of the 14 patients who underwent revision, 9 underwent decompression with or without instrumented fusion, 2 patients had removal of the X-Stop for implant pain, and 2 patients had removal at an outside institution. The reasoning for the latter two patients was not stated. One patient had a revision of the X-Stop due to traumatic dislocation. The Kaplan-Meier survivorship curve yielded a 68% survival at 48 months. Eleven patients underwent revision within the first 18 months, of which all had continuing or return of preoperative symptoms. Three patients underwent revision at 3 to 4 years after the X-Stop procedure. These three patients had improvement of symptoms during the above period prior to revision. The authors concluded that the results of the X-Stop may not always be favorable, and patient selection is critical.[26]

Though as yet unpublished, Zucherman's group reviewed their complications with the use of the X-Stop device. Three-hundred patients were identified from January 2006 to August 2007 with one- to three-level X-Stop implantation. The average age was 74, with follow-up ranging from 3 to 4.5 years. Twenty patients (6.7%) encountered complications, of which 10 required further surgical intervention. Complications included six failures, five device migrations or spinous process fractures, three new radiculopathies, one compression fracture, one infection, one hematoma, and three medical complications. All six failures went on to revision, three were removed, and one patient underwent laminectomy with posterior fusion.[27]

35.8 Expanded Indications

[1] Advancement of the use of the X-Stop has been developed. As noted previously, the spinous process load to failure correlates with the patient's bone mineral density. It can be projected that the lower the T-score on a dual-energy X-ray absorptiometry (DEXA) scan, the higher the risk of spinous process fracture, thus failure of the X-Stop device. Idler et al created a study to evaluate the use of polymethyl methacrylate (PMMA) injected into the spinous process to enhance the strength of the entire X-Stop construct. Nine cadavers were used. Motion segments from each cadaver were dissected and divided into the control and PMMA groups. Two cubic centimeters of PMMA were injected into the spinous processes with an 11-gauge needle. The mean load failure and stiffness were calculated in each group with axial loading of 1 cm/min until failure. Bone mineral densities were obtained from each of the nine specimens, with an average of 0.99. The mean load to failure of the X-Stop construct for the control group was 1,250 N. The mean load to failure of the X-Stop PMMA construct was 2,386 N. The authors found a linear correlation between the bone mineral density and failure load and stiffness. The authors concluded that augmentation of the spinous process with PMMA increases the failure load as well as the stiffness of the X-Stop construct and potentially can be incorporated into in vivo use.[28] Zucherman et al conducted a prospective study assessing the use of PMMA augmentation in vivo.[29] Two hundred forty patients with a diagnosis of osteoporosis or osteopenia based on DEXA scan were included. All patients had a minimum 1-year follow-up. Seventy-seven patients were in the PMMA augmentation group with X-Stop implantation, and 163 patients were in the control group with X-Stop implantation only. ODI score, walking and standing times, patient satisfaction, as well as VAS were used for outcome measures. Cementation techniques were also assessed separately. Overall, the authors found an average improvement of ODI for the PMMA group was 18.7 and 14.3 for the control group. No statistical difference was noted between the two groups. Standing and walking times as well as satisfaction rates were also similar. When the PMMA group was subclassified based on cementation technique, statistically significant improvement in ODI score[2] was seen in those was grade 3 (full cementation of

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the spinous process) when compared with the control group[29] (▶ Fig. 35.2).

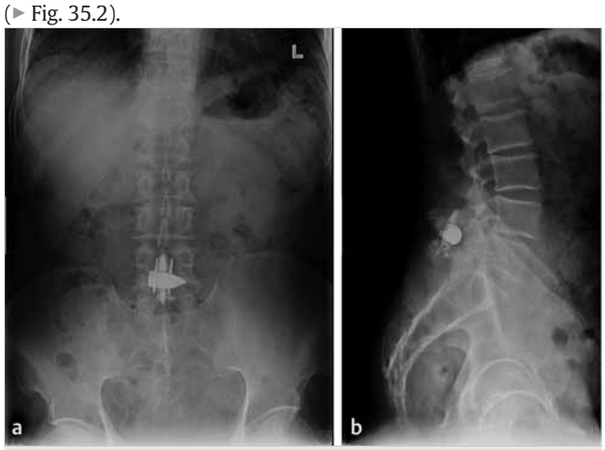

Fig. 35.2 a, b (**a**) Upright lumbar radiographs with polymethyl methacrylate augmentation. (**b**) X-Stop (Medtronic).

Outcomes of the X-Stop application and age have been assessed. Romero et al conducted a retrospective review of 255 patients who underwent an X-Stop procedure over the course of 1 year.[30] Minimum follow-up was 1 year, and ODI scores were used to measure outcome. Patients were divided into two [1] groups by age—those older than 70 and those younger than 70. The authors found that ODI scores, amount of time standing, and amount of time walking were improved in those patients who were younger than 70 compared with those older than 70. This was statistically significant.[30]

In some patients, the degree of spinal stenosis can be quite severe, such that an X-Stop application alone is insufficient, particularly in cases of severe subarticular and foraminal stenosis. Fuchs et al reviewed the stability of the lumbar spine with graded facetectomies and X-Stop implantation.[31] Seven cadaveric specimens were gathered with assessment of L2–L3, L3–L4, and L4–L5. Graded facetectomies included a unilateral medial facetectomy, unilateral total facetectomy, and bilateral total facetectomy. Rotation, flexion, extension, and neutral positions were measured using camera images with specimens undergoing facetectomies with and without X-Stop application. Axial loading of 700 N and 7.5 Nm was used for bending moments. The authors found that bilateral total facetectomies significantly increased flexion and lateral bending range of motion. Unilateral medial facetectomy and unilateral total facetectomy did not result in significant destabilization and may be done in the setting of X-Stop application.[31]

Facet cysts arise from degenerative facet joints and may be present in lumbar spinal stenosis as space-occupying lesions. Abrams et al conducted a retrospective review of 285 patients who underwent X-Stop application over the course of 5 years at a single institution.[32] Fifty-eight (20.4%) of the patients were found to have synovial cysts contributing to stenosis. Mean follow-up was 22 months. The ODI and VAS scores of those patients with and those without facet cysts were compared. No statistically significant difference was noted between those with and without facet cysts in patients treated with the X-Stop. The authors concluded that the X-Stop is successful in the treatment of lumbar stenosis with the presence of facet cysts.[32]

The original investigational device exemption (IDE) study by [2] Zucherman et al included patients with up to grade I spondylolisthesis. Anderson et al conducted a multicenter randomized controlled study looking specifically at the efficacy of X-Stop use in patients with grade 1 spondylolisthesis and spinal stenosis.[33] Nine centers randomized 191 patients with symptomatic lumbar spinal stenosis who met the original criteria listed earlier, as well as spondylolisthesis of 5 to 25%. Patients were seen at 6 weeks, 6, 12, and 24 months postoperatively. The ZCQ and SF-36 were used for the outcome measures. No patients in the control group study crossed over to the X-Stop group. Five patients in the X-Stop group and four patients in the control group underwent surgical decompression with laminectomy. On radiographic review, there was no statistically significant increase in spondylolisthesis or kyphosis at 2-year radiographic follow-up. At 2-year follow-up, 63.4% of the X-Stop group had improved ZCQ scores compared with 12.9% in the control group.[33]

The relationship of scoliosis and the X-Stop has been reviewed. Rolfe et al retrospectively reviewed 179 patients with a minimum 1-year follow-up between January 2006 and May 2007 who had an X-Stop placed, ranging from one to three levels.[34] Of these, 116 patients had a less than 10 degree curve, 41 patients had a curve between 11 and 25 degrees, and 22 patients had a 26 to 55-degree curve. ODI scores were used to calculate outcome. In their results, the authors found that ODI scores improved in all groups after X-Stop placement; however, improvement was less profound when the curvature increased beyond 23 to 28 degrees.[34]

35.9 Summary

The X-Stop is designed to limit terminal extension at stenotic levels of the lumbar spine and relieve symptoms of lumbar spinal stenosis. This has been confirmed by imaging studies to increase both the central canal and foraminal area. It is a procedure that can be performed without general anesthesia and in an outpatient setting for patients with symptomatic lumbar spinal stenosis. It has been shown to be relatively safe in the appropriate patient population with symptomatic relief out to 5 years.

35.10 References

[1] Spivak JM. Degenerative lumbar spinal stenosis. J Bone Joint Surg Am 1998; 80: 1053–1066
[2] Verbiest H. A radicular syndrome from developmental narrowing of the lumbar vertebral canal. J Bone Joint Surg Br 1954; 36-B: 230–237
[3] Sengupta DK, Herkowitz HN. Lumbar spinal stenosis. Treatment strategies and indications for surgery. Orthop Clin North Am 2003; 34: 281–295
[4] Weinstein JN, Tosteson TD, Lurie JD et al. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the Spine Patient Outcomes Research Trial. Spine 2010; 35: 1329–1338
[5] Zucherman JF, Hsu KY, Hartjen CA et al. A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. Eur Spine J 2004; 13: 22–31
[6] Kondrashov DG, Hannibal M, Hsu KY, Zucherman JF. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year follow-up study. J Spinal Disord Tech 2006; 19: 323–327
[7] Zucherman JF, Hsu KY, Hartjen CA et al. 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. Spine 2005; 30: 1351–1358

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[8] Hsu KY, Zucherman JF, Hartjen CA et al. Quality of life of lumbar stenosis-treated patients in whom the X STOP interspinous device was implanted. J Neurosurg Spine 2006; 5: 500–507

[9] Pratt RK, Fairbank JC, Virr A. The reliability of the Shuttle Walking Test, the Swiss Spinal Stenosis Questionnaire, the Oxford Spinal Stenosis Score, and the Oswestry Disability Index in the assessment of patients with lumbar spinal stenosis. Spine 2002; 27: 84–91

[10] Zucherman J, et al. Five Year Outcomes in Patients with the XStop Interspinous Process Device for Neurogenic Intermittant Claudication Due to Lumbar Spinal Stenosis. Toronto, ON: North American Spine Society; 2008

1

[11] Schmid MR, Stucki G, Duewell S, Wildermuth S, Romanowski B, Hodler J. Changes in cross-sectional measurements of the spinal canal and intervertebral foramina as a function of body position: in vivo studies on an open-configuration MR system. AJR Am J Roentgenol 1999; 172: 1095–1102

[12] Fujiwara A, An HS, Lim TH, Haughton VM. Morphologic changes in the lumbar intervertebral foramen due to flexion-extension, lateral bending, and axial rotation: an in vitro anatomic and biomechanical study. Spine 2001; 26: 876–882

[13] Siddiqui M, Karadimas E, Nicol M, Smith FW, Wardlaw D. Influence of X Stop on neural foramina and spinal canal area in spinal stenosis. Spine 2006; 31: 2958–2962

[14] Lee J, Hida K, Seki T, Iwasaki Y, Minoru A. An interspinous process distractor (X STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases. J Spinal Disord Tech 2004; 17: 72–77, discussion 78

[15] Idler C, et al. Long term Xstop interspinous process decompression follow-up comparing pre and post operative MRI canal and foramen area. Presented at: 8th Annual Global Symposium on Motion Preservation Technology, Spine Arthroplasty Society; 2008; Miami Beach, Florida

2

[16] Siddiqui M, Karadimas E, Nicol M, Smith FW, Wardlaw D. Effects of X-STOP device on sagittal lumbar spine kinematics in spinal stenosis. J Spinal Disord Tech 2006; 19: 328–333

[17] Schulte LM, O'Brien JR, Matteini LE, Yu WD. Change in sagittal balance with placement of an interspinous spacer. Spine 2011; 36: E1302–E1305

[18] Lindsey DP, Swanson KE, Fuchs P, Hsu KY, Zucherman JF, Yerby SA. The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. Spine 2003; 28: 2192–2197

[19] Talwar V, Lindsey DP, Fredrick A, Hsu KY, Zucherman JF, Yerby SA. Insertion loads of the X STOP interspinous process distraction system designed to treat neurogenic intermittent claudication. Eur Spine J 2006; 15: 908–912

[20] Swanson KE, Lindsey DP, Hsu KY, Zucherman JF, Yerby SA. The effects of an interspinous implant on intervertebral disc pressures. Spine 2003; 28: 26–32

[21] Wiseman CM, Lindsey DP, Fredrick AD, Yerby SA. The effect of an interspinous process implant on facet loading during extension. Spine 2005; 30: 903–907

[22] Skidmore G, Ackerman SJ, Bergin C et al. Cost-effectiveness of the X-STOP® interspinous spacer for lumbar spinal stenosis. Spine 2011; 36: E345–E356

[23] Burnett MG, Stein SC, Bartels RH. Cost-effectiveness of current treatment strategies for lumbar spinal stenosis: nonsurgical care, laminectomy, and X-STOP. J Neurosurg Spine 2010; 13: 39–46

[24] Kondrashov D, Hannibal M, Hsu K, Zucherman J. X-Stop versus decompression for neurogenic claudication: economic and clinical analysis. Internet Journal of Minimally Invasive Spinal Technology 2005;1(2)

[25] Bowers C, Amini A, Dailey AT, Schmidt MH. Dynamic interspinous process stabilization: review of complications associated with the X-Stop device. Neurosurg Focus 2010; 28: E8

[26] Tuschel A, Chavanne A, Eder C, Meissl M, Becker P, Ogon M. Implant survival analysis and failure modes of the X STOP interspinous distraction device. Spine 201 3; 38: 1826–1831

[27] Iezza A, et al. Analysis of Complications with XStop. Goteborg, Sweden: International Society for the Study of the Lumbar Spine; 2011

3

[28] Idler C, Zucherman JF, Yerby S, Hsu KY, Hannibal M, Kondrashov D. A novel technique of intra-spinous process injection of PMMA to augment the strength of an inter-spinous process device such as the X STOP. Spine 2008; 33: 452–456

[29] Zucherman J, et al. Use PMMA Augmentation in Osteopenic/Osteoporotic Patients Treated with the Xstop Device for Neurogenic Intermittant Claudication. In Proceedings of the International Society for the Study of the Lumbar Spine; May 2009; South Beach, Miami, FL

4

[30] Romero N, et al. Outcome versus Age: A Retrospective Patient Chart Review After X-Stop Decompression, in International Society for the Advancement of Spine Surgery. April 2010 Poster: New Orleans, LA

5

[31] Fuchs PD, Lindsey DP, Hsu KY, Zucherman JF, Yerby SA. The use of an interspinous implant in conjunction with a graded facetectomy procedure. Spine 2005; 30: 1266–1272, discussion 1273–1274

[32] Abrams J, Hsu K, Kondrashov D, McDermott T, Zucherman J. Treatment of facet cysts associated with neurogenic intermittent claudication with x-stop. J Spinal Disord Tech 2013; 26: 218–221

[33] Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. J Neurosurg Spine 2006; 4: 463–471

[34] Rolfe KW, Zucherman JF, Kondrashov DG, Hsu KY, Nosova E. Scoliosis and interspinous decompression with the X-STOP: prospective minimum 1-year outcomes in lumbar spinal stenosis. Spine J 2010; 10: 972–978

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