

CHAPTER 32: CLINICAL RESULTS OF THE IDE TRIAL OF X-STOP

INTERSPINOUS SYSTEMS

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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. Stenosis 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 age of greater than fifty.

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 patient. 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 treatment to operative treatment. The natural history of spinal stenosis is variable with 45% of patient remaining stable, 15% of patients improving, and 30% of patients declining.[3]

Treatment

Nonoperative treatment includes medication, bracing, physical therapy, as well as epidural steroid injections. When comparing nonoperative treatment with that of surgical decompression,

a study by Weinstein, et. al. conducted a multicenter randomized control trial as well as an observational cohort group. The multicenter study included thirteen centers within the US with a follow-up of up to four years. Outcomes were measured at 6 weeks, 3 months, 6 months and yearly with outcome measures of SF-36 and Oswestry Disability index scoring. The study found that patients who have 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 to the continued nonoperative group.[4]

Operative intervention

The goal of operative intervention is decompression of the thecal sac. Multiple procedures have been described to include, but not limited to, laminectomy, laminotomy, and insertion of an interspinous process distraction system. This chapter will focus on the application of the interspinous process distraction system, specifically the X-stop device. [Figure 1](#)

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 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. al. conducted a multi-center prospective randomized study looking at the first year's results. Nine centers participated in the study with two hundred patients randomized from May of 2000 to July of 2001. Patients included had either an MRI or CT which demonstrated one or two levels of stenosis. One hundred patients were randomized into the X-stop group and ninety-one were

randomized into the nonoperative group. Nine patients withdrew from the study after their randomization. Non-operative treatment included one or more epidural steroid injection, nonsteroidal anti-inflammatory medication, analgesics, as well as physical therapy and/or bracing. Mean age of the X-Stop group was 70 and 69 years of age in the non-operative group. Average duration of symptoms between the two groups was between three to four 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 after treatment. 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 improvement ZCQ scores as well as SF-36 scores compared to the randomized non-operative group. The authors concluded that at 1 year, patients with neurogenic claudication significantly improved with X-stop treatment compared to non-operative treatment with similar reoperation rates.[5]

The same group reviewed their results at two and four years.[6, 7] At two years follow-up, ninety-three of the one-hundred X-stop patients and eight-one of the ninety-one of the nonoperative patients were available for follow-up. Six of the 93 patients in the X-stop group and twenty-four of the 81 patients treated nonoperatively underwent decompression surgery by two years. When reviewing imaging studies, 96% of the X-stop group had maintenance of distraction at 2 years. 48.4% of the X-stop group patients improved in the ZCQ score compared to 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 years follow-up using the SF-36 scoring. They gathered the bodily pain, general health, mental and physical component, physical functioning, emotion and physical role as well as social function aspect of the outcome form. At two years, they found

statistically significant improvement in all areas, except general health, emotional role and mental component when compared to 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 four years, Kondrashov et. al. noted eighteen 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 Oswestry disability index (ODI). Improvement was noted when comparing preoperative ODI of 45 (range 20 to 80) and postoperative ODI of 15 (range 0 to 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 Zucherman et. al., has been gathered and analyzed. Twenty-eight patients with a minimum of five year follow-up had undergone X-stop placement with the same criteria from the original X-stop study discussed previously. Average age was 67.5 years. Zurich claudication questionnaire was used for outcome measures. Preoperative outcomes compared to 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 five years thus far.[10]

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. Schmid et. al. reviewed MRIs of twelve volunteers with a mean age of 28. No patient had an abnormal MRI, to include disc pathology. MRIs were obtained in the seated upright neutral, seated upright flexed, seated upright extended and supine extended position. Two radiologists read the MRIs 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 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 disk; whereas, there was no change in cross sectional area at the pedicular level. When looking at the ligamentum flavum, there was an increase in thickness with seated upright extension compared to flexion of approximately three-fold. When assessing the neural foramen, there was a mean decrease of cross sectional area of 23.2% when comparing seated upright flexion and extension at each disc level of L1 to S1. There was a 19.2% increase in cross sectional area when comparing the seated upright neutral position with the seated upright flexion position. The authors concluded that 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. 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 years old. The MRIs were obtained with the patients in the erect position, sitting neutral, flexion and extension position. The authors noted a statistically significant increase in the spinal canal area in the erect and seated upright neutral position compared to the preoperative area in single level X-stops. At double level X-stops, there was 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 position.[13] Another study had similar results. A review of 10 patients who underwent the X-stop application and followed for a minimum of nine months demonstrated an increase in the cross sectional area of the dural sac of 22.3% and neural foramen of 36.5% from preoperative to postoperative MRI.[14] 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 endplate angles were also measured. There was noted statistically significant increase in canal area from 1.27 cm² to 1.42 cm² and a foraminal area increase from 0.54 cm² to 0.97 cm². There was no difference in disc height or endplate angles.[15]

Concerns have been raised on the effect of sagittal balance secondary to the device. Siddique's group reviewed the same twenty-six patients noted above and looked at the effects of motion and disc height and angulation on the patients with X-stops. Preoperative and

postoperative MRIs were obtained in the standing, seated upright neutral, flexion and extension as well as supine position. Disc heights were measured in the seated flexion and extension position as well as supine and erect position. Lumbar motion was measured from superior endplates of L1 and S1 in the upright seated extension and flexion position. The authors' results showed that there was no significant difference in lumbar curvature pre and postoperatively. There was noted 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 twenty patients who underwent an X-stop. All patients had 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 done in five patients, two level X-stop in fourteen patients, and three level X-stop in one patient. Sagittal balance was found to have improved in sixteen of the twenty patients and decline in four of the twenty patients. Mean change in sagittal balance was -2.0cm.[17]

Lindsey, et. al., additionally, looked into the results of the range of motion of the lumbar spine as well as the adjacent lumbar levels with X-stop implantation. Seven cadaveric models were employed. L2-L5 were studied with the donors ranging from 17 to 55 years of age. Flexion, extension, lateral bending and axial rotation were assessed. One level X-stop was performed each level independently. It was found that at L3-L4 and L4-L5, the range of motion of extension was significantly reduced at these levels of implantation. The overall range of motion of L2-L5 from 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]

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 and ease of administration under local anesthesia, many elderly, osteoporotic and appropriately fearful patients are especially attracted to the procedures as are their surgeons. The insertional load to failure of the X-stop and the spinous process load to failure was studied by Talwar et. al. 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 was measured. Seven cadaveric specimens were used 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 Newtons and the mean spinous process load to failure was 316.9 Newtons. The mean load to failure at the areas 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 BMD 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 of 56 to 80 years of age. Each disc from L2 through L5 was subjected to 700 Newtons of axial pressure with intradiscal pressure measured with the spine in neutral, extended and flexed position. 7.5 Nm was used for the bending moment. 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 L3-4 (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 L2-3 and L4-5. [20]

Wiseman, et. al. assessed the pressure on the facet joints in extension with implantation of the X-stop. Seven lumbar cadaveric models were used to assess the L2-3, L3-4, and L4-5 facet joints. All specimens were axially loaded with 700 Newtons and facet joint pressure were measured using pressure films. 15 Nm extension moment was applied and pressure film was remeasured. An X-stop was then placed at L3-4 and the models were retested. Results showed 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 facets levels.[21]

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. A literature review was conducted as well as formulation of a cost-effectiveness analysis based on a multicenter, randomized study of 131 patients. Data collection of medical reimbursement, medicare reimbursements, and estimated medical costs were gathered for 2 years time. 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. A literature review was conducted as well as a cost-effectiveness model was created to look at the direct health care costs with the use of mean case numbers and reimbursements of sixteen 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 outpatient procedures. The two surgical groups also had the additional cost of the nonoperative group. At two years time, the authors concluded that laminectomy was the most effective treatment, followed by X-stop and lastly nonoperative treatment.[23]

Kondrashov et. al. retrospectively reviewed eighteen patients with X-stop placement at one or two levels with age-matched patients who underwent laminectomy decompression. Both groups had similar length follow-up of a little greater than 4 years. The X-stop procedure was performed as an outpatient. Average hospital costs for each procedure were assessed. The authors concluded that when directly comparing the X-stop and laminectomy procedure 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]

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. Thirteen patients with moderate or severe spinal stenosis had X-stop application at L4-L5 and L3-4. Average age of the patients was 75 years. All but one patient had regular follow-up intervals within two years postoperatively. All patients were contacted at four years postoperatively. All patients had improvement in back and leg pain after surgery; however, ten patients' pain returned (77%). The authors noted complications of 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 they had an 85% complication rate and that X-stop may not be as beneficial for patients with moderate to severe spinal stenosis and careful patient selection is imperative.[25]

Survival analysis was retrospectively assessed by Tuschel et. al. at a single institution forty-six patients who underwent a total of sixty-one X-stops. The mean age was 68.2 years with thirty-one one level X-stop and fifteen patients with two level X-stops. Mean follow-up was 34 months. Five patients did not meet follow-up criteria and fourteen 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) 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 fourteen patients that underwent revision, nine

underwent decompression with or without instrumented fusion, two patients had removal of the X-stop for implant pain, and two 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. 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 3-4 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 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 levels X-stop implantation. Average age was 74 years with follow-up ranging from 3 to 4.5 years. Twenty patients (6.7%) encountered complications, of which ten required further surgical intervention. Complications included 6 failures, 5 device migration or spinous process fracture, 3 new radiculopathy, 1 compression fracture, 1 infection, 1 hematoma, and 3 medical complications. All 6 failures went onto revision, 3 were removed and 1 patient underwent laminectomy with posterior fusion.[27]

Expanded indications

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 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 PMMA injected

into the spinous process to enhance the strength of entire X-stop construct. Nine cadavers were used. Motion segments from each cadaver were dissected and divided into the control and PMMA group. Two cubic centimeters of PMMA were injected into the spinous processes with an 11 gauge needle. The mean load failure and stiffness was calculated in each group with axial loading of 1cm/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 1250 Newtons. The mean load to failure of the X-stop PMMA construct was 2386 Newtons. They found a linear correlation between the BMD and failure load and stiffness. The authors concluded that augmentation of the spinous process with PMMA increases that failure load as well as 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. Two-hundred forty patients with a diagnosis of osteoporosis or osteopenia based on DEXA scan were included. All patients had a minimum one year follow-up. Seventy-seven patients were in the PMMA augmentation group with X-stop implantation and one-hundred sixty-three patients were in the control group with X-stop implantation only. Oswestry disability index score, walking and standing times, patient satisfaction, as well as visual analog scale 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 was seen in those was grade 3 (full cementation of the spinous process) when compared to the control group.[29] [Figure 2 and 3](#)

Outcomes of the X-stop application and age has been assessed. Romero, et. al. conducted a retrospective review of two hundred fifty-five patients who underwent an X-stop over the course of one year. Minimum follow-up was one year and ODI scores were used to measure outcome. Patients were divided into two groups: greater than 70 years of age and those younger than 70 years of age. The authors found that ODI scores, amount of time standing as well as walking was improved in those patients who were younger than 70 compared to those older than 70. This was statistically significant..[30]

In some patients, the degree of spinal stenosis can be quite severe that an X-stop application alone is not enough, particularly severe subarticular and foraminal stenosis. Fuchs, et. al. reviewed the stability of the lumbar spine with graded facetectomies and X-stop implantation. 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. 700 Newtons of axial loading and 7.5 Nm were 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 two hundred eighty-five patients who underwent X-stop application over the course of five years at a single institution. Fifty-eight (20.4%) of the patients were found to have synovial cysts contributing to stenosis. Mean follow-up was 22 months. Comparison of the ODI and VAS

were conducted between those patients with and without facet cysts. 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 IDE study by Zucherman, et. al. included patients with up to grade I spondylolisthesis. Anderson, et. al. conducted a multicenter randomized control study looking specifically at the efficacy of X-stop use in patients with grade 1 spondylolisthesis and spinal stenosis. Nine centers randomized one hundred ninety-one patients with symptomatic lumbar spinal stenosis who met the original criteria listed above, as well as spondylolisthesis of 5 to 25%. Patients were seen at six weeks, six, twelve, and twenty four months postoperatively. Zurich claudication questionnaire and SF-36 was 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 two year radiographic follow-up. At two year follow-up, 63.4% of the X-stop group had improved ZCQ scores compared to 12.9% in the control group. [33]

The relationship of scoliosis and the X-stop has been reviewed. Rolfe, et. al. retrospectively reviewed one-hundred seventy-nine 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. One hundred-sixteen patients had a less than 10 degree curve, forty-one patients had between an 11-25 degree curve and twenty-two patients had over a 26 degree curve, with a maximum of 55 degrees. Oswestry disability 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]

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 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 five years.

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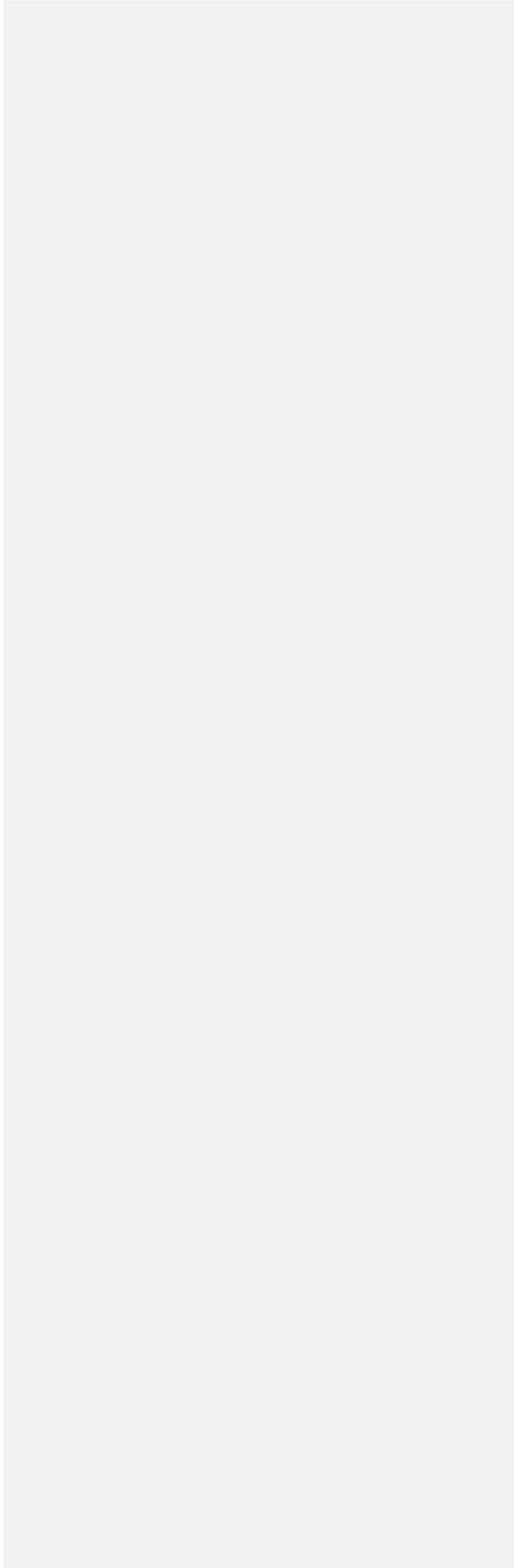
Figure 1

Polyetheretherketone X-stop implant.



Figure 2 and 3:

Upright lumbar radiographs with PMMA augmentation and X-stop.



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