Neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis (LSS) is a posture-dependent complaint and it typically affects patients at the age of 50 years or older. NIC is defined as pain or numbness in the buttocks, thighs, and/or lower legs caused by decrease of the spinal canal area and brought on by either prolonged standing or exercise in the erect posture. The symptom is typically relieved by various maneuvers that flex the lumbar spine, which increases the spinal canal area significantly (1-9).

Decompressive surgery with or without fusion is the current gold standard treatment for moderate to severe symptomatic LSS.

**INTERSPINOUS PROCESS DECOMPRESSION (IPD)**

A new minimally invasive, stand-alone alternative to conservative and standard surgical decompressive treatments has been developed (10-13). The interspinous implant (X STOP, St. Francis Medical Technologies Inc., Alameda CA) is placed between the spinous processes to prevent extension of the symptomatic levels, yet allowing flexion, axial rotation, and lateral bending (Fig. 23.1)(14). Eliminating the symptomatic extension at the abnormal segment and keeping it in that position would maintain the asymptomatic state and allow the more normal spinal segments to function normally. The patient would no longer be forced to keep the entire lumbar spine in flexion just to maintain enough space at the localized stenotic areas.

Because the load-bearing element is anterior to the retained supraspinous ligament a cantilever effect results unloading the middle column of the spine while restoring height loss from degenerative changes. This is born out by biomechanical testing mentioned later. Also the retained posterior supraspinous ligament prevents kyphotic deformity as is verified by the radiographic studies mentioned later. The load that is taken up by the device is taken from the middle column of the spine, which has deteriorated from its inability to efficiently handle loads over the years. This then may allow slowing of the degenerative process or even some recovery of inflamed chronically overloaded tissues over time as is evidenced by the persistence of benefit from the device with a 78% success rate at 4-year follow-up based on

![Figure 23.1](image-url) X STOP interspinous implant.
Oswestry Disability Index (ODI) scores (15). Because sagittal balance effect is minimal, motion limitation is minimal, and adjacent disc and facet joint pressures are unaffected, there is no reason to believe the device will adversely affect the natural history of adjacent segments.

Biomechanical studies have shown that, in extension, the implant significantly increases the canal area by 18%, the subarticular diameter by 50%, the canal diameter by 10%, the foraminal area by 25%, and the foraminal width by 41%. These dimensions were not affected at adjacent levels. This is the primary mechanism of action (16). Wardlaw et al. reported equal results in their clinical study evaluating positional magnetic resonance imaging (MRI) changes after X STOP implantation (17,18). Further studies have also demonstrated that at the implanted level, the implant significantly reduces the pressure on the facets, in the nucleus pulposus, and in the posterior annulus of the disc, without influence on adjacent levels (16,19,20).

**SURGICAL PROCEDURE**

Patients may be operated on under local anesthesia with light intravenous sedation, placed in either lateral decubitus or prone position. A 4- to 8-cm midline incision is made exposing the spinous processes at the appropriate disc level, which is confirmed radiographically. The supraspinous ligament and its attachments are preserved, which is of paramount importance to prevent postoperative kyphosis and also to serve to stabilize the implant. The interspinous ligament is pierced, but retained, and the implant is placed between the spinous processes. The spinous processes are not modified to allow implantation, but in cases where hypertrophied facets protrude posteriorly, they should be trimmed without interfering its integrity in function (Fig. 23.2). The spinal canal is not violated, and neither laminotomy, nor laminectomy, nor foraminotomy is performed. Removal of any portion of the ligamentum flavum is unnecessary.

**CLINICAL RESULTS IN LITERATURE**

**X STOP Prospective Randomized Multicenter Study**

Based on very promising results of a clinical pilot study of ten symptomatic LSS patients treated with the X STOP, a United States Food and Drug Administration (US FDA) prospective randomized clinical multicenter study was undertaken, comparing the interspinous implant with conservative (nonoperative) treatment for the management of NIC. Study results demonstrated a clinically and statistically significant difference favoring the interspinous implant. Two years after the surgery, 60% of the patients reported that their symptoms were significantly improved, compared to 18% of the control patients. Regarding physical function, 57% of X STOP patients reported significant improvement, compared to 15% of control patients. Among X STOP patients, 73% were satisfied or very satisfied with their treatment compared to 36% of the control group patients (Table 23.1) (21).

Of interest, 39 patients with grade I degenerative spondylolisthesis were treated in the U.S. study with the X STOP and 22 patients were treated nonoperatively. Using 15-point improvement over baseline scores in the Zurich Claudication Questionnaire
FIGURE 23.2 The X STOP interspinous process decompression (IPD) implant procedure.
TABLE 23.1 Zurich Claudication Questionnaire (ZCQ) Success Rates 2 Years After Surgery

<table>
<thead>
<tr>
<th>Success Rates</th>
<th>X STOP (N = 93)</th>
<th>Control (N = 81)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom severity</td>
<td>60%</td>
<td>19%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physical function</td>
<td>57%</td>
<td>15%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>73%</td>
<td>36%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

(ZCQ) as the criterion of clinical success, 69% of the X STOP patients had a successful outcome at 2-year follow-up, compared to 9% of the control patients. The mean improvement score for the 39 X STOP patients was 26 points. There were no significant differences in the mean percentage of slip between X STOP and control patients at baseline or at 2-year follow-up. The X STOP represents a significantly less invasive alternative therapy for these patients, resulting in very good clinical outcomes, and most importantly, no evidence that the implant results in any instability of the motion segment. In this study, more than a third of the patients treated with the X STOP implant suffered from a degenerative spondylolisthesis up to grade 1 (out of 4). Spondylolisthesis patients are mostly treated with an instrumented spinal fusion. Analysis of this subgroup showed that the X STOP procedure is as effective as that applied on patients without spondylolisthesis(22).

Furthermore, Implicito et al.(23) reported on their subanalysis of the X STOP patients in this study, comparing 63 one-level and 33 double-level IPD patients. With the current surgical options, NIC patients treated surgically at multiple levels typically have worse outcomes than those treated at one level. This study showed that both X STOP groups had significant improvements postoperatively (p < 0.0001). The success rate of the one-level IPD patients was 56% and for the two-level IPD patients it was 73%, with no significant difference between the success rates, showing the X STOP to be an effective way to surgically treat patients with NIC at more than one level.

Sagittal Balance

The requirement to maintain proper sagittal alignment and balance in patients receiving spinal implants is well understood. Experience with lumbar fusion procedures that cause a flat back has overwhelmingly resulted in unacceptable clinical outcomes. Three different radiologic studies were therefore undertaken to measure any possible effect of the X STOP on sagittal alignment. In the U.S. study, x-rays were taken at each follow-up visit for both X STOP and control patients and measurements were made of the lumbar-sacral angle (L1 to S1) and the treated intervertebral angle. At 2-year follow-up, there were no significant differences in the mean scores between the two groups of patients. Preoperative x-rays from a subset of X STOP patients were also compared to standing films taken at 2-year follow-up. In 23 patients with single-level implants, the change in the intervertebral angle was only 0.5 degree (±2.0 degrees), and the change in the
lumbosacral angle was 0.1 degree (±3.8 degrees). Similar values were recorded for 18 patients with double-level implants.

Interim data from an ongoing study being conducted at the University of Aberdeen by Wardlaw and Smith (24) have been recently presented, in which preoperative images were compared to post implant images obtained in a positional MRI scanner. In addition to confirming in vivo the increases in the area of the foramen and canal that were measured in the preclinical in vitro cadaver study, results of this study confirm a change in angulation for both the lumbosacral angle and intervertebral angle of between 1 and 2 degrees. These three studies confirm that the X STOP results in only minimal changes to sagittal alignment. This due is to preserving the supraspinous ligament and its original insertions. This ligament is a very robust structure receiving the confluence of the lumbodorsal fascia and its preservation prevents overdistracton of the segment.

**X STOP Versus Decompressive Laminectomy**

The success rate of decompressive surgery varies greatly due to a number of factors such as patient selection, surgical technique, and outcome measures. An attempted meta-analysis of 74 surgical LSS studies reported a mean rate of good to excellent outcomes of 64% in the first year (25).

Compared to literature-reported outcomes of decompressive surgery there are significant differences in operative time, estimated blood loss, hospital stay, complication rate, and reoperation rates, favoring the X STOP IPD (26–38) (Table 23.2).

During the course of the U.S. study, 24 patients in the control group underwent decompressive laminectomy for the relief of their stenosis symptoms and outcomes are available for 22 patients. At a mean follow-up time of 12.8 months outcomes for these patients were very similar to outcomes of the X STOP patients at 2-year follow-up. Sixty-four percent had clinically significant improvement in Symptom Severity Domain of ZCQ, 68% had clinically significantly improvement in Physical Function Domain of ZCQ, and 60% were satisfied with the outcome of their treatment. Furthermore, Katz et al. (39) published a large series of surgically treated spinal stenosis patients using the ZCQ outcomes tool. When the same success criteria that were used in the X STOP series are applied to Dr. Katz’s series, the results in all three domains are equivalent for two surgical procedures (40).

**TABLE 23.2 X STOP Decompression Versus Laminectomy**

<table>
<thead>
<tr>
<th>Operative and Hospitalization Details</th>
<th>X STOP</th>
<th>Laminectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average OR time (minutes)</td>
<td>27–54</td>
<td>104–224</td>
</tr>
<tr>
<td>Average blood loss (mL)</td>
<td>46</td>
<td>120–1,040</td>
</tr>
<tr>
<td>Average length of hospital stay</td>
<td>&lt; 24 hours–2 days</td>
<td>7–8 days</td>
</tr>
<tr>
<td>Operative or device-related complications</td>
<td>7%</td>
<td>20% (with arthrodesis)</td>
</tr>
<tr>
<td>Reoperation rate</td>
<td>6%</td>
<td>10%–23%</td>
</tr>
</tbody>
</table>

OR, operating room.
Both the multicenter randomized clinical trial (RCT) study in the United States and Strömqvist et al. (41) as part of the Swedish national register of lumbar surgery, used the SF-36 to evaluate general health outcomes after surgical treatment. A comparison between two matched subsets of patients, 90 each, showed that the postoperative scores were improved for both groups in all domains except for general health 1 year after surgery. Mean postoperative scores in the two physical and emotional domains improved more markedly for the X STOP group (42).

Okumu and Hannibal (43) evaluated the cost and effectiveness of X STOP and laminectomy surgery during index hospitalization for the treatment of 33 patients with LSS in the United States. Patients were matched for age, number of levels treated, and preoperative disability. It was shown that X STOP is significantly more cost-effective than laminectomy for the treatment of single- and double-level LSS (Table 23.3).

Turner et al. (25) reported on complications such as dural tears, neural injuries, deep wound infections, pulmonary embolism, myocardial infarction, and death in their meta-analysis of 74 LSS surgery studies. To date, with the exception of a death that occurred 3 days postoperatively and was determined to be unrelated to the X STOP implant, there were no complications of this nature reported during or after the X STOP procedure.

German Registry

In Germany, a registry is being maintained to gather prospective data on NIC patients, who are treated with the X STOP implant in general practice. Patients are assessed pre- and postoperatively using the validated, condition-specific ZCQ. The ZCQ is the only validated LSS-specific outcomes measure (46,47). The questionnaire consists of three domains: Symptom Severity (SS), Physical Function (PF), and Patient Satisfaction (PS). To date 212 patients have been evaluated 1 year after surgery with very good results (Table 23.4). Two patients had a reoperation because of lack of efficacy and one because of dislocation of the implant.

<table>
<thead>
<tr>
<th>TABLE 23.3 X STOP Versus Laminectomy: Average Hospital Costs for Single- and Double-Level Lumbar Spinal Stenosis (LSS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laminectomy</strong></td>
</tr>
<tr>
<td>1 level</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Hospital charges</td>
</tr>
<tr>
<td>Lab/ECG</td>
</tr>
<tr>
<td>OR/OR supplies</td>
</tr>
<tr>
<td>X-rays</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Anesthesia</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Subtotal</td>
</tr>
<tr>
<td>Hardware (est)</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

ECG, electrocardiogram; OR, operating room.
CHAPTER 23 X STOP Interspinous Implant for Lumbar Spinal Decompression

TABLE 23.4 Zurich Claudication Questionnaire (ZCQ) Success Rates 6 and 12 Months After Surgery

<table>
<thead>
<tr>
<th>Symptom severity</th>
<th>Physical function</th>
<th>Patient satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>82%</td>
<td>81%</td>
<td>82%</td>
</tr>
<tr>
<td>82%</td>
<td>77%</td>
<td>82%</td>
</tr>
</tbody>
</table>

In addition to the German results presented here, Katz et al. (33) reported outcomes with 2-year follow-up on 197 NIC patients treated with a lumbar laminectomy using the same success criteria in a patient population similar to those enrolled in the registry.

The German X STOP patients show higher ZCQ success rates compared to the scores of the laminectomy patients reported by Katz et al. (Fig. 23.3).

European Clinical Experience

A prospective clinical evaluation of 15 patients with 3- and 6-month follow-up was carried out by Wardlaw (46) in conjunction with pre- and postoperative positional MRI scan measurements. All cases demonstrated clinical improvement and the X STOP implant increased the cross-sectional area of the dural sac and exit foramina without affecting overall movement of the lumbar spine.

Heijnen and Kramer (47) reported on the satisfaction of 14 patients with NIC, who were treated with the X STOP implant. One patient died of a non-back related disorder. Eleven of the other 13 patients expressed a great satisfaction. They are free of NIC symptoms and all but one would undergo the surgery again, if the choice had to be made again.

SCIENTIFIC EVIDENCE X STOP IN PERSPECTIVE TO WORLDWIDE LITERATURE

Surgery for Degenerative Lumbar Spondylosis

Gibson and Waddell (48) evaluated the current scientific evidence on the effectiveness of surgical interventions for degenerative lumbar spondylosis, involving surgical procedures of spinal decompression, nerve root decompression, and fusion of adjacent vertebra.

Thirty-one published RCTs of all forms of surgical treatment for degenerative lumbar spondylosis were identified. There is moderate evidence that instrumentation can increase the fusion rate, but strong evidence that it does not improve clinical outcomes.

The trials varied a lot in quality: only in 16, more recent, trials there was some form of centralized
randomization scheme or assignment system. Eighteen of the 31 trials had the recommended follow-up for surgical studies of at least 2 years. Only 6 trials reported on the surgical treatment for spinal stenosis and/or nerve root decompression. Just 1 of the 6 trials was an RCT with a large patient population, it concerns the prospective randomized clinical multicenter study, comparing the X STOP interspinous implant with conservative (nonoperative) treatment (Table 23.5).

Turner et al. (25) also reported on the poor scientific quality of the published studies in their attempted meta-analysis of 74 surgical therapy studies for LSS. None of the 74 studies were randomized and just 8 studies were clearly prospective.

CONCLUSION

The decompression of the lumbar spine with X STOP IPD implant offers a well-proven, safe, effective, and cost-effective treatment of patients suffering from NIC secondary to LSS. The X STOP can be implanted with local anesthetic, and many patients can return home within 24 hours after surgery.

In brief, regarding X STOP decompression of the lumbar spine:

- It is clinically well proven as an effective treatment for symptoms of LSS with or without degenerative spondylolisthesis.
- It is safe.
- It has a short surgery time and can be made under local anesthesia.
- It is minimally invasive.

| TABLE 23.5 Scientific Review on Degenerative Spondylosis; The Cochrane Review 2005 |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| No. Randomized Controlled Trials | 16              | No              | Decompression vs. decompression with fusion  |
| No. Clinical Controlled Trials  | 15              | No              | Different surgical decompression techniques |
| TOTAL                           | 31              | No              | Decompression vs. decompression with fusion  |
| Six trials on spinal and nerve root stenosis |
| Author                          | Year | No. Patients | Randomized | Subject                                    |
| Herkowitz                       | 1991 | 50           | No         | Decompression vs. decompression with fusion |
| Postacchini                     | 1993 | 70           | No         | Different surgical decompression techniques |
| Bridwell                        | 1993 | 44           | No         | Decompression vs. decompression with fusion |
| Grob                            | 1995 | 45           | No         | Decompression vs. decompression with fusion |
| Amundsen                        | 2000 | 31           | No         | Surgical Decompression vs. conservative     |
| Zucherman                       | 2004 | 200          | Yes        | X STOP vs. conservative treatment incl. epidural injections |
• It can be implanted during a short stationary or ambulatory stay.
• There is an immediate and subsistent relief of pain.
• It is cost-effective.

The X STOP implant offers the benefits of decompression, yet with a low-risk profile, for NIC patients.

The comparative analyses suggest that the outcomes of the X STOP decompression may at least be comparable to outcomes reported in the literature for decompressive laminectomy. However, mainly due to flaws in studies on decompressive treatments, no definitive conclusions can be drawn.

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