Interspinous Process Decompression for Neurogenic Intermittent Claudication Secondary to Degenerative Lumbar Spinal Stenosis

a report by
Patrick Simons

Department of NeuroSurgery, MediaPark Klinik

Introduction

Lumbar spinal stenosis (LSS) is a condition involving the narrowing of either the spinal canal or neural foramina. The stenosis is caused by hypertrophy of the ligament flavum and facet joints, osteophytes, spondylolisthesis and disc protrusion, which results in nerve compression in one or more motion segments.\textsuperscript{1-5}

The most common symptom associated with LSS is neurogenic intermittent claudication (NIC) and typically concerns patients at the age of 50 or above. NIC is defined as pain or numbness in the buttocks, thighs and/or legs brought on by either prolonged standing or exercise in the erect posture. The symptom is typically relieved by various manoeuvres that flex the lumbar spine, such as bending forward or sitting, which increases the spinal canal significantly.\textsuperscript{2-10} 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, standalone alternative to conservative and decompressive treatments\textsuperscript{11-14} has been developed. The interspinous implant (X STOP\textsuperscript{8}) is placed between the spinous processes to prevent extension of the symptomatic levels but allow flexion, axial rotation and lateral bending.\textsuperscript{15}

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 and this is the primary mechanism of action.\textsuperscript{16} Wardlaw et al. reported equal results in their study evaluating positional magnetic resonance imaging (MRI) changes after X STOP implantation.\textsuperscript{17,18} Further studies have demonstrated that the implant significantly reduces pressure on the facets\textsuperscript{19} at the implanted level by 63\%. Furthermore, it reduces pressure in the nucleus pulposus by 41\% and in the posterior annulus of the disc by 63\%. Kinematic studies demonstrated that there is no influence on adjacent levels.\textsuperscript{1,5,20}

Surgical Procedure

Patients may be operated on under local anaesthesia with light intravenous (IV) sedation and are positioned in a flexed position (either lateral decubitus or prone position). A 4-8cm mid-line incision is made exposing the spinous processes, thighs and/or legs brought on by either prolonged standing or exercise in the erect posture. The symptom is typically relieved by various manoeuvres that flex the lumbar spine, such as bending forward or sitting, which increases the spinal canal significantly.\textsuperscript{2-10} Decompressive surgery with or without fusion is the current ‘gold standard’ treatment for moderate to severe symptomatic LSS.

Clinical Results in Literature

Early in 1997, 10 patients with symptomatic LSS underwent implantation of the interspinous implant in a clinical pilot study. Eight out of 10 patients showed some level of improvement in symptom severity, physical function, walking distance or all three. On the basis of the very promising results, a prospective randomised multi-centre study comparing patients treated with the X STOP with conservative (non-operative) treatment was undertaken in the US with approval from the US Food and Drug Administration (FDA). The patients studied were suffering from NIC secondary to mild to moderate LSS. Study results demonstrated a clinically and statistically significant difference favouring the X STOP.\textsuperscript{21} Two years after the surgery, 60\% of the patients reported that their symptoms were significantly improved compared with 18\% of the control patients. Regarding physical function, 57\% of X STOP patients reported significant improvement compared with
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15% of control patients. Among X STOP patients, 73% were satisfied or very satisfied with their treatment compared with 36% of the control group patients.

In the US study, more than one-third of the X STOP patients suffered from a degenerative spondylolisthesis up to grade 1 (of four grades). The clinical importance of this group is based on the fact that these patients are usually treated with an instrumented spinal fusion. Analysis of this subgroup showed that the X STOP procedure is as effective when applied to patients without spondylolisthesis.

X STOP IPD Compared with Decompressive Surgery

Studies of decompressive laminectomy patients have shown that 30% to 70% of patients report significant symptom improvement. A meta-analysis of 74 surgical therapy studies for LSS shows an average rate of 64% with 'good' or 'excellent' results in the course of the first year. Compared with literature-reported outcomes of laminectomy surgery there are significant differences in operative time, estimated blood loss, hospital stay, complication rate and reoperation rates favouring the X STOP.

Turner et al. reported on complications such as dural fissures, nerve injuries, deep wound infections, embolism of the lung, epidural haematoma, myocardial infarction (MI) and death in their meta-analysis of 74 studies of lumbar spinal stenosis surgery. With the exception of a death that occurred three days post-operatively and was determined to be unrelated to the X STOP device (cause of death was pulmonary oedema in a patient with a significant history of cardiovascular disease), there were no complications of this nature reported during or after the X STOP procedure.

Both the multicentre study in the US and Strömquist et al., as a part of the Swedish national register of lumbar surgery, used the SF-36 to evaluate general health outcomes after surgical treatment. A comparison between matched subsets of 90 patients each showed that, one year after surgery, the post-operative scores were improved for both groups in all domains except for general health. Mean post-operative scores improved more markedly (more than 10%) for the X STOP group in the two physical and emotional domains.
German Registry

Currently, a registry is being maintained in Germany to gather prospective data on NIC patients, who are treated with the X STOP in general practice. The patients are assessed pre- and post-operatively using the validated, condition-specific Zurich Claudication Questionnaire (ZCQ). The ZCQ is the only validated, spinal stenosis specific outcome measure. The questionnaire consists of three domains – symptom severity (SS), physical function (PF) and patient satisfaction (PS). To date, 55 of 111 patients have been evaluated one year after surgery with good results. Table 3 shows the ZCQ success rates.

In addition to the German results presented, Katz et al. reported outcomes with two-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 this registry. The German X STOP patients show higher ZCQ-success rates compared with the laminectomy patients reported by Katz et al. (see Figure 2).

Pre-treatment scores in the SS domain of the German group tended to be worse compared with the laminectomy patients reported by Katz et al. The German X STOP group showed significantly better absolute and relative ZCQ outcomes compared with the scores of the laminectomy patients by Katz et al. (see Figure 3).

Conclusion

The decompression of the lumbar spine with X STOP IPD offers a safe and effective treatment for patients suffering with neurogenic intermittent claudication as a result of a lumbar spinal stenosis. The X STOP can be implanted with local anaesthetic and many patients can return home within 24 hours after surgery.

In brief, regarding the X STOP procedure for decompression of the vertebral processes:

- it is clinically proven as an effective treatment for the symptoms of LSS with or without a degenerative spondylolisthesis;
- it is safe;
- it has a short surgical duration and can be carried out under local anaesthesia;
- it is minimally invasive;
- it can be implanted during a short stationary or ambulatory stay;
- there is an immediate and subsistent relief of pain; and
- it is cost-effective.

X STOP IPD offers the benefits of decompression with a low risk profile for patients suffering from NIC secondary to LSS.

While no definitive conclusions can be drawn, the comparative analyses suggest that the outcomes of the X STOP surgery may at least be comparable with outcomes reported in the literature for laminectomy patients.

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