Background: Patients who present with leg pain caused by stenosis can also present with a complaint of activity related back pain. This can be related to the stenosis itself, and other times caused directly by the degenerative changes of the segment. These patients are typically treated with decompression and spinal fusion. While decompression alone can result in significant instability of the treated segment and subsequent restenosis, early fusion may facilitate early degeneration and stenosis of the adjacent levels. The dynamic posterior spinal stabilization system LimiFlex (Simpirica Spine Inc, CA, USA) has been developed to limit flexion of the segment, thereby reducing forces borne by the disc, addressing the low back pain and stabilizing segments without the need for fusion. Here we are presenting initial six-month results of a prospective patient surveillance study to evaluate the clinical and radiological outcomes in patients treated with the LimiFlex device.

Material and methods: 30 patients (12 males and 18 females) with low back pain and leg pain due to spinal stenosis and degenerative disc disease were treated with interlaminar decompression of one to four levels. Five patients also showed degenerative listhesis Meyerding grade I. Discectomy was performed on three patients with combined discogenic stenosis. The LimiFlex device was placed after decompression was completed on the treated level. For patients with multi-level decompression, the segment of highest instability as assessed by Meyerding grade, angular motion on preoperative radiographs, or intraoperative findings of instability, was stabilized. Three times the implant was placed at L2/3, twelve times at L3/4 and fifteen times at L4/5. Follow-up was completed at three and six month after surgery, and data was available for 26 patients (87%) at six month time point. Preoperatively and during the follow-ups, patients were assessed through self-reported Visual Analog Scale (VAS), and the Oswestry Disability Index (ODI) was documented, along with Odom's criteria and patient satisfaction. Adverse events (AE) and serious adverse events (SAE) were logged. All clinical data was monitored through an independent clinical trial monitor. Outcome of functional radiographic scans pre- and postoperatively and at follow ups was assessed, and the segmental alignment was evaluated for any signs of instability.

Results: At the six month follow up, the median pain scores (VAS) of both back and leg pain were improved significantly from pre- to post-intervention as were the ODI, and the pain free walking distance (subset 4 of ODI). Odom's criteria were good to excellent in all but two patients assessed, and patient satisfaction with surgery was above 90% at six month. Four patients had SAEs, none of them related to the implant. Radiographic assessment showed no increase of segmental instability after decompression on levels treated with LimiFlex.

Conclusion: Interlaminar decompression with LimiFlex stabilization in patients presenting with leg pain and activity-related back pain due to spinal stenosis and degenerative disc disease led to a significant clinical improvement in pain and function. Segmental instability after decompression was avoided. Further long-term results are needed to evaluate if adjacent level stenosis and re-stenosis of treated levels can be avoided, and if this procedure is superior to interbody fusion in early stages of degenerative disc disease.