

## ISIS 18th Annual Scientific Meeting

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### **Abstract Title:**

Six-Week Follow-up of Patients Treated with Vertos *mild*® Prospective Single Center Results

### **Background:**

The Vertos commercially-available *mild* instruments allow access to the lumbar spine and removal of tissue contributing to spinal stenosis. The *mild* devices are utilized for tissue access, retraction and resection within the lumbar spine via a minimally invasive dorsal approach. Using the *mild* devices, the desired intra-operative outcome is lumbar spinal decompression. The *mild* procedure is conducted through a 5.1mm access portal and utilizes fluoroscopic guidance to assess anatomical landmarks and guide the instruments.

### **Objectives:**

The purpose of this report is to characterize and assess the clinical application and outcomes of Minimally Invasive Lumbar Decompression with the *mild* devices in patients with symptomatic central canal spinal stenosis treated at a single center.

### **Methods:**

To date, six-week follow-up is available for 20 patients with symptomatic lumbar spinal stenosis who met Study enrollment criteria and were treated with the *mild* procedure. Visual Analog Score (VAS) and Oswestry Disability Index (ODI) assessments have been made at baseline and follow-up. Device and procedure-related significant adverse events have been documented.

### **Results:**

Eleven of twenty patients (55%) were female, and mean age was 76 years, with a range of 51 to 89 years. There were no reports of dural tears, blood transfusions, hematomas or nerve root damage and the rate of serious adverse events was 0%. VAS and ODI protocol success were defined as number of points improved from baseline. The change from baseline to Week 6 was statistically significantly improved in both VAS (reduced pain) and ODI (increased functional mobility).

### **Discussion:**

The *mild* procedure is conducted percutaneously through an introducer cannula, the *mild* Portal. Fluoroscopic imaging in the AP caudal-cranial and lateral-oblique planes is utilized to assess anatomical landmarks and guide the instruments to the lamina, through the interlaminar space and into the ligamentum flavum in the posterior spine for tissue removal. The *mild* devices can be engaged within tissue, under or aside bony structures, and manipulated using image guidance.

The *mild* ultra-minimally invasive lumbar decompression procedure can be performed with local anesthetic and moderate sedation. The procedure involves no implants, and results in little tissue trauma allowing very rapid recovery. The small portal site is closed with a sterile adhesive strip, with no need for sutures.

**Conclusion:**

This report of six-week follow-up on the initial 20 patients at a single center, indicates that the *mild* procedure is safe, and that patients experience statistically significant improvement in both VAS and ODI scores. Patients continue to be treated at our site, and follow-up is documented for all patients treated with the *mild* procedure. Expanded patient efficacy data will be reported as available.