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## **FOR IMMEDIATE RELEASE**

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### **New Data Show Lasting Effects and No Serious Adverse Events with a Percutaneous Decompression Procedure for Lumbar Spinal Stenosis Patients**

March 25, 2011, National Harbor, MD—Patients treated for lumbar spinal stenosis (LSS) with the *mild* decompression procedure (an alternative to open spinal surgery for many patients), reported sustained improvements in pain and mobility at one year and had no serious adverse events occur, according to the first multi-center one-year post-study follow-up of this patient cohort. Results from this prospective, evidence-based study were presented today at the American Academy of Pain Medicine's 27th Annual Meeting.

The post-study results were presented by Timothy R. Deer MD, of The Center for Pain Relief in Charleston, West Virginia. Outcomes of the procedure were assessed one year post treatment for all available patients who had participated in the first *mild* multi-center U.S. clinical trial completed last year. Included in the report were 170 procedures, mostly bilateral at one or two affected levels, in fifty-eight patients who were treated with the *mild* therapy.

Four validated outcome instruments were used including the Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and the SF-12v2® Health Survey. The study patients achieved a significant improvement in pain (40

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percent pain reduction) with VAS scoring improving in 79 percent of the patients, from overall mean 7.4 pre-treatment to 4.5 at Year One. Functional mobility also improved in 71 percent of the patients with overall mean ODI improving from 48.6 (severe disability) to 36.7 (moderate disability). The ZCQ and SF-12v2 measures also showed statistically and clinically significant improvements in pain and physical function, as well as satisfaction with overall result after the procedure.

“We did find that the functional criteria, as measured in an objective fashion, were statistically and significantly better after the *mild* procedure than at baseline,” comments Dr. Deer.

Safety was assessed by close patient monitoring for any serious device or procedure-related adverse event. At one year, there were zero significant adverse outcomes such as dural tear, blood transfusion, nerve root damage, or hematoma. The alternative treatment for LSS patients who have failed conservative treatment is open spinal surgery, where there is a 9 to 20 percent rate of serious adverse outcomes, which makes the *mild* an attractive option for these patients.

“The fact that this is the first one year prospective, evidence-based study is very encouraging because there is very little one-year data on spine procedures in recent literature. This prospective study allowed us to gather data directly from the patients in real time, decreasing the biased data that is often accompanied with retrospective studies,” Dr. Deer concludes.

As many as 6 million Americans suffer from LSS, which reduces the space in the spinal canal causing pressure on the nerves, resulting in painful symptoms. Common causative factors include hypertrophic ligamentum flavum, facet hypertrophy, and disc protrusion.

A minimally invasive spine surgery for LSS, the *mild* procedure utilizes percutaneous access to perform a decompression laminotomy with epidurogram and fluoroscopic image guidance. This procedure restores space and relieves pressure on the spine (spinal decompression) using specialized *mild* devices and a local anesthetic with conscious sedation.

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The American Academy of Pain Medicine is the premiere medical association for pain physicians and their treatment teams with over 2,600 members. Now in its 27th year of service, the Academy's mission is to optimize the health of patients in pain and eliminate it as a major public health problem by advancing the practice and the specialty of pain medicine through education, training, advocacy and research. Information is available on the practice of pain medicine at [www.painmed.org](http://www.painmed.org).

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