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Abstract Submission

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Abstract Title:

Comparative Study of Epidural Steroid Injection versus *mild*® (minimally invasive lumbar decompression) Procedure in Patients Diagnosed with Symptomatic Moderate to Severe Lumbar Spinal Stenosis

Background:

Various minimally invasive and surgical options are used to perform lumbar decompressive procedures. The goal of the *mild* procedure is to effect a decompression with minimal surrounding tissue disruption. The standard medical therapy widely used to treat symptomatic lumbar spinal stenosis is a combination of pain medicine, epidural steroids (ESI) and/or physical therapy. Where conservative therapy fails, the common surgical procedures involve various techniques that range from an insertion of an interspinous decompression implant to moderate endoscopic or major open surgery. These all may result in various amounts of damage to large areas of tissue, muscle, ligaments and bone in the back. Recovery from the major surgical procedures is painful and can require several months of low activity and rest.

Objectives:

The purpose of this single-center, randomized, prospective, double-blind, cross-over clinical study is to assess the clinical application, safety and Patient Reported Outcomes (PRO) with *mild* devices versus epidural steroid injection in patients with symptomatic moderate to severe lumbar spinal stenosis.

Methods:

Patients with symptomatic lumbar spinal stenosis who meet the study enrollment criteria are randomized to either ESI or the *mild* procedure. Patients are treated with the *mild* procedure under radiographic image guidance as described in the *mild* product labeling, or with ESI. Neither the enrolling physician nor the subject are aware of the subject's ultimate treatment group. Patients are unblinded at six weeks and allowed to cross over to the other treatment group, if desired. All patients are followed for a period of up to six months after final treatment in order to assess patient outcomes. Enrollment includes up to 40 adult patients at one study center.

Baseline documentation of pain medication usage, neurological examination, Visual Analog Score (VAS), Quality of Life (SF-12), Oswestry Disability Index (ODI), and Zurich Claudication Questionnaire (ZCQ) are made prior to study treatment. Patient follow-up via telephone survey and office visits includes documentation of the same above measures and any medication changes. Device and procedure-related significant adverse events are documented throughout the study period.

Results:

Enrollment is continuing for this study, and is anticipated to be completed by November 2010. Safety is evaluated for both groups by comprehensive records of both solicited and unsolicited reports of device or procedure-related adverse events. Patient cross-over rate in each group will be monitored.

Discussion and Conclusion:

Thus far, this unique study design has demonstrated comparable safety profiles for the two treatment groups. Device and procedure-related adverse events were absent in both groups, indicating that these procedures are safe. A majority of ESI patients treated to date chose to cross over to *mild* at six weeks, suggesting the need for further treatment in the ESI group. Conversely, none of the *mild* patients have elected to cross over to ESI.