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Abstract Submission

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Abstract Title:

mild[®] (Minimally Invasive Lumbar Decompression)—Report of Single-Center Safety Results vs. Meta-Safety

Background:

mild is a minimally invasive treatment for pain relief from symptomatic lumbar spinal stenosis (LSS). LSS is a common problem caused by many factors, the most common being ligamentum flavum hypertrophy. The *mild* technique provides removal of small but adequate amounts of ligament and lamina, avoiding the need for aggressive resection of bone and muscle and/or surgical implants. During the *mild* procedure, bone and ligament sculpting devices are passed through a small 6G Portal, under fluoroscopic visualization, to achieve decompression.

Objective:

To compare single-center safety results to a broad meta-safety analysis of patients treated with *mild*.

Methods:

Safety of the *mild* procedure was collected for thirty patients at this institution, and for over 250 patients in the meta-safety analysis used for comparison. The meta-analysis included patients treated at over 20 institutions. Patients were treated with the *mild* procedure for symptomatic lumbar spinal stenosis. Device and procedure-related significant adverse events were documented throughout the study. Patient Reported Outcomes (PRO) are being collected to be presented in future reports. Safety and outcomes were assessed from baseline to six weeks post-treatment.

Results:

There were no device or procedure-related serious adverse events in either the single center clinical cases, or those included in the meta-analysis. Serious complications are defined as dural tears, nerve root damage, post-op infection requiring surgical intervention, hemodynamic instability and post-op spinal structural instability. Additionally, no reports of blood transfusions, epidural bleeding or hematomas were reported.

Conclusions:

The *mild* procedure is a safe method for the treatment of LSS. *mild* offers a safe early option for the treatment of LSS following failed conservative therapy, but prior to more invasive surgical treatment.